TOWARDS A NATIONAL BIODEFENSE STRATEGEY

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TOWARDS A NATIONAL BIODEFENSE STRATEGY

Thursday, June 3, 2004

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON HOMELAND SECURITY,
Washington, DC.

The committee met, pursuant to call, at 1:13 p.m., in Room 345, Cannon House Office Building, Hon. Christopher Cox [chairman of the committee] presiding.

Present: Representatives Cox, Dunn, Barton, Shays, Camp, Goodlatte, Linder, Thornberry, Turner, Dicks, Lowey, McCarthy, Jackson Lee, Christensen, Lucas, Langevin, and Meek.

Chairman COX. The Select Committee on Homeland Security will come to order. The committee is meeting today to hear testimony on the development of a national biodefense strategy. In order to allow us to hear from our witnesses more quickly, I would ask members to waive or limit the duration of oral opening statements. Those who are present within 5 minutes of the gavel and waive their opening statement will be allotted 3 additional minutes for questioning the panel. If the members have written statements, they may be included in the hearing record.

I want to thank our distinguished panelists for appearing before us this afternoon.

The biothreat is particularly worrisome because we know so little about terrorist capabilities. We don't know nearly as much as we would like about their motivations and their intentions to employ biological weapons. Yet, we also know that a bioattack could result in a catastrophic loss of life. The Department of Homeland Security must have experienced analysts to assess the threat on a continuing basis, and must play a leading role in coordinating the development of antidotes and countermeasures to the most virulent agents we face today and that we will face tomorrow.

As the President stated soon after 9/11, disease has long been the deadliest enemy of mankind. Infectious diseases make no distinctions among people and recognize no borders. We have fought the causes and consequences of disease throughout history, and must continue to do so with every available means. Of course, this goes triply if those diseases are being spread intentionally rather than by mother nature.

Under President Bush's leadership, we have stood up the new Department of Homeland Security, substantially increasing biosecurity through the passage of the Bioterrorism Preparedness Act of 2002, and we have begun implementation of the latest Presidential directive on biosecurity, HSPD–10. We have also dramati-

cally increased funding for biodefense research, surveillance, preparedness, and response activities.

The House and now the Senate have also passed the project BioShield Act, which hopefully soon will go to the President's desk for signature. This bipartisan legislation is an investment to incentivize development of the counter-measures by the private sector and speed up biodefense research. It is only one of many initiatives the President has proposed and fully supported to counter the continued biothreat.

The serious and continuing threat to our citizens is real. The President's and Congress' commitment to reducing it is today greater than ever. The good news is that our investments in biodefense will have significant application to naturally-occurring infectious diseases that can, with little warning, wreak havoc on mankind without regard to borders or social class.

The science and technology revolution in which we are now involved offers unprecedented hope, if we are smart enough, to exploit the opportunities before us. Over the past year, DHS's highly capable science and technology directorate has implemented biowatch in approximately 30 cities. The President's commitment to building a strong biodefense is clear in the fiscal year 2005 budget proposal. R&D biodefense spending in the science and technology directorate alone is slated for a 42 percent increase over fiscal year 2004 levels. The S&T directorate and its current management has enjoyed the enthusiastic support of both the Executive and Legislative Branches. And we expect this to continue.

That said, we must all recognize that the time has come to develop and implement a clear national strategy for biodefense that will allow us to focus on priorities, to discipline our spending, and to permit measurement toward concrete goals. The strategy presented by the President in the Homeland Security Presidential Directive 10, Biodefense for the 21st Century, defines the missions, sets the priorities, and assigns roles to key Federal partners. It gives the Department of Homeland Security specific responsibilities to coordinate these efforts. The committee will conduct rigorous oversight of DHS's efforts to develop a concrete strategy to implement this new directive.

The panel before us represents the primary Federal partners assigned to mitigate the biothreat. As our committee moves to complete the first authorization bill for the Department of Homeland Security, we will be especially vigilant in assessing DHS efforts to craft a biodefense strategy.

We must address the paramount need to prioritize research goals and objectives in consultation with the widest range of U.S. government and outside experts. As this committee so often stresses, credible intelligence will be a key factor in this prioritizing. I look forward to hearing the steps our witnesses have taken to work with the IAIP directorate and other elements of the intelligence community to incorporate our best intelligence into your planning for biodefense R&D and to levy new requirements to improve that intelligence. I also look forward to hearing the progress you have made in surveillance, detection, and diagnosis of bioterrorist threat agencies.

Finally, we know only too well that an effective biodefense strategy must include unprecedented cooperation among Federal agencies. The Department of Homeland Security along with the Department of Health and Human Services and the Department of Defense, must coordinate their resources as never before to defeat the biothreat. Close coordination among these Federal departments will be increasingly important to develop the scientific expertise and R&D capabilities to meet the threat of new and more virulent agents in the year ahead.

I, again, thank our distinguished witnesses for taking the time to be with us this afternoon. And at this time, I would yield to the gentleman from Texas, Mr. Turner, for his opening statement.

Mr. TURNER. Thank you, Mr. Chairman. It is good to have all of our witnesses here today to talk about this very, very important subject to Homeland Security.

I want to thank all of our witnesses for their presence, Dr. Albright, Dr. Fauci, welcome back to our committee. We look forward to hearing from both of you once again. General Martinez and Dr. Raub, thank you so much for your presence here today. I also want to thank Dr. Shelley Hearne, who will appear momentarily to give us perspective on biodefense preparedness as well as Dr. Anna Johnson-Winegar, who has years of experience as a researcher and administrator of biological defense programs.

It was one year ago that this committee held hearings on Project Bio-Shield. Following such consideration, we, along with our House colleagues, moved quickly to approve the bill, sending it to the Senate. Its final passage out of the Senate just two weeks ago is, in my judgment, long overdue, and I think once again, illustrates for us the fact that, in my judgment, we have lost the sense of urgency that we need to have for protecting the homeland that we all felt in the wake of the 9/11 attacks. The sense of urgency must be regained. I think we all understand that our terrorist enemies who are fully capable of striking again and looking for opportunities to do so.

Fortunately, we have made some progress in preparing our Nation to combat a bio-terrorism attack. We do have a large strategic national stockpile of antibiotics and medical supplies. Public servants such as Dr. Fauci have worked hard to develop new vaccines, drugs, diagnostic devices, all of which we need in the defense against bio-terrorism.

Our Department of Homeland Security has deployed new sensors to detect airborne pathogens in our major cities, and the Department of Defense has long made the protection of troops from chemical and biological weapons a priority of its research and procurement programs.

Despite this good news, there is clear evidence that we need to do a whole lot more. We need to move much faster in protecting our Nation against the threat of bio-terrorism. Let me cite a few examples.

It took us 2–1/2 years after the anthrax attacks to develop a strategy for bio-terrorism, a strategy that was released just a few weeks ago by the administration in the form of a Presidential directive. In reviewing this document, it appears from our briefings on the subject that it sets forth broad strategic goals and assigns

specific tasks to specific agencies. It does not, however, seem to identify specific objectives, establish time frames for achieving those objectives, allocate resources, or clearly define the roles of the Federal, state, and local agencies in bio-terrorism prevention, preparedness, and response. In order to get this job done, this degree of detail must be attached to and provided as a part of this strategic plan to deal with the bioterrorist threat.

Another example of our failure is that we still have not secured our national stocks of dangerous pathogens and the laboratories that house them, despite a requirement to do so in the 2002 Bioterrorism Preparedness Act.

While expanded research is essential to improving our biodefense, it also brings more opportunities for the accidental or intentional escape of pathogens from legitimate facilities. The administration should fully implement the select agent regulations mandated by Congress as soon as possible.

Another example of a shortcoming I think that still exists: While we have enough smallpox vaccine, from what I understand, to vaccinate every man, woman, and child in the Nation, it appears to me that it is still an open question as to whether or not we could vaccinate our population quickly enough if a smallpox outbreak occurred. The administration's goal of vaccinating 500,000 health care workers and first responders has not been met. The last time I checked, we had vaccinated under 50,000 people. And 40 percent of the States report that they are unable to vaccinate their populations within 10 days of an outbreak. The goals of the national smallpox vaccination program have not been achieved, and it is not clear how the administration is attempting to get that program back on track.

In addition to the deficiencies in smallpox preparation, the trust for America's health reports that only two States are actually prepared to distribute the supplies that currently reside in the national stockpile. To prepare our Nation for a bioterrorist attack, every State and community in the country should have detailed plans outlining how the necessary medicines will be transported, where the medicines will be distributed, and who will be operating those distribution centers.

Finally, Mr. Chairman, we need to acknowledge that while Project BioShield is a good first step, it is unlikely to provide the full range of countermeasures we need to prepare this Nation for a bioterrorist attack. We must take steps to ensure that the private sector and, if necessary, the Federal government can rapidly produce the counter-measures we need to combat the unknown, the resistant, or the bioengineered pathogens that could be used against us in a future bioterror attack.

That is why I, along with 34 other Members of the House, recently introduced H.R. 4258, the Rapid Cures Act, to begin the process of building a national capability to respond more quickly to bioterrorism threats. And I hope that each of our witnesses will take a look at that legislation and advise me regarding your opinion and the merits of it.

The legislation recognizes that it may never be possible to produce every medical countermeasure we need through Project BioShield, and that the growing power of biotechnology can render

a pathogen like anthrax or smallpox immune to the vaccines and drugs that we do have on hand. We need to develop the mechanisms to go from bug to drug or the identification of a pathogen to the development of a countermeasure to combat it in as little as a few months or even weeks rather than the current 18-year average for drug development. Personally, I cannot think of another research goal that would bring more benefits to the security of this country and to the public health of this country than achieving this objective. I am interested in hearing from our witnesses today on this proposal.

Mr. Chairman, bioterrorism is arguably the most significant threat we face, and I thank you for calling the hearing today to allow us to examine how we best move forward to develop a bioterrorism strategy for our nation.

Thank you, Mr. Chairman.

Chairman COX. I thank the gentleman.

The gentleman from Connecticut, the chairman of the Subcommittee on National Security of the Committee on Government Reform and Oversight, is recognized for purposes of an opening statement.

Mr. SHAYS. I have no opening statement. I will just have questions. Thank you.

Chairman COX. The gentleman from Michigan.

Mr. CAMP. I am fine.

Ms. MCCARTHY. I yield back.

Chairman COX. Does any member wish to be recognized for purposes of an opening statement? If not, the Chair will now call up testimony from the first panel. Let me remind witnesses that under our committee rules they should strive to limit their opening remarks to 5 minutes. Each witness's entire written statement will appear in the record. We will also allow the entire panel to testify before questioning any witnesses.

Chairman COX. The Chair now recognizes our first witness, the Honorable Penrose "Parney" Albright, Assistant Secretary for Science and Technology, the Department of Homeland Security, to testify. Secretary Albright, welcome back to the Committee on Homeland Security.

STATEMENT OF THE HONORABLE PENROSE "Parney" ALBRIGHT

Dr. ALBRIGHT. Thank you, Chairman Cox. And good afternoon, Chairman, Congressman Turner, and the other distinguished members of the committee. I am pleased to appear before you today to discuss the progress of the science and technology directorate of the Department of Homeland Security, that it is making in the Nation's effort to prevent, protect against, respond to, and recover from acts of bioterrorism against the American people.

President Bush has made strengthening the Nation's defenses against biological weapons a critical national priority. And, as the Chairman just pointed out, this has resulted in a joint Homeland Security Presidential directive, along with the National Security Council, entitled Biodefense for the 21st Century, that provides a comprehensive framework for our Nation's biodefense.

The Department of Homeland Security, through the science and technology directorate, has explicit responsibilities in this integrated national effort.

I want to briefly address how we work with the Department of Homeland Security's information, analysis, and infrastructure protection directorate and how their work is linked to the S&T directorate's work. The IAIP directorate assesses collected intelligence and information about threats and vulnerabilities from other agencies, and then takes preventative and protective action. They are partners in the total agencies to obtain, assess, and disseminate information regarding potential threats to America from terrorist actions. These threats and vulnerability assessments are inputs into the strategy and research, development, testing and evaluation activities of the science and technology directorate, and further inform S&T's interactions with the broader research and development community.

The Presidential directive, Biodefense for the 21st Century, outlines four essential pillars of the Nation's biodefense program and provides specific directives to further strengthen the significant gains that have been put in place in the past 3 years.

The four pillars of the program are:

First, threat awareness, which includes biological weapons-related intelligence, vulnerability assessments, and anticipation of future threats. And then, prevention and protection, surveillance and detection, and response and recovery.

The Department of Homeland Security and S&T directorate have a role and responsibility in each of these four pillars of the national biodefense program. Our contributions and planned activities include providing a continuing all-WMD assessment effort within the science and technology directorate. This work is being performed for IAIP. The first reports describing the capabilities of 20 terrorist groups in biological, chemical, radiological, nuclear, cyber, and advanced explosives threats areas have been completed and delivered to IAIP.

Furthermore, the S&T directorate has embedded a team of WMD scientific experts to provide technical assistance to IAIP analysts, and is installing a knowledge information tool within IAIP to enable easy access to reports and all the supporting data and information.

The S&T directorate has established a national biodefense analysis and countermeasure center, or NBACC, with the missions of threat characterization, forensics and attribution, and the establishment of a knowledge center in the biological area. The S&T directorate is further coordinating with the Departments of Defense, Health and Human Services, and Agriculture to establish a national interagency biodefense campus at Fort Detrick. The S&T directorate addresses the full range of biological threats, but the initial emphasis is on active defense against high consequence threats, those that can inflict damage that would significantly challenge this Nation's immediate ability to respond.

In addressing these biological threats, the S&T directorate has the leadership role in several key areas and partners with lead agencies in others. Those areas in which the S&T directorate provides significant leadership are, first, providing an overall end-to-

end understanding of an integrated biodefense so as to guide the Secretary and the rest of the Department in its responsibility to coordinate the Nation's efforts to deter, detect, and respond to biological acts of terrorism.

We also provide scientific support, as I mentioned earlier, to the intelligence community and IAIP in prioritizing the biothreats. We are, again, as the Chairman noted, developing and have implemented early warning and detection systems to permit timely response to mitigate the consequences of the biological attack. And we conduct technical forensics to analyze and interpret materials recovered from an attack to support attribution.

DHS also supports our partnering departments and agencies where they are leads in other key areas of an integrated biodefense. The Department of Health and Human Services on medical countermeasures and mass casualty response, USDA on agriculture, USDA and HHS on food security, and the Environmental Protection Agency on decontamination and on water security.

The Presidential directive HSPD–10, as well as other HSPDs, identify national objectives and priorities and departmental agency roles in addressing those particular national priorities in the biodefense arena. The S&T directorate has been and continues to be an active participant in interagency activities. We participated in the joint NSC/HSC biodefense end-to-end study, which led directly to HSPD–10, and this was followed by an interagency review conducted under the aegis of the NSC/HSC for fiscal year 2006 to 2010 science and technology needs to support the national biodefense strategy as articulated in HSPD–10.

This and other inputs including those from the counterproliferation technology coordinating committee, the National Science and Technology Council's weapons of mass destruction medical countermeasures committee, and its associated subcommittees, and various HHS-led risk management meetings which help guide medical countermeasure procurements, are being documented in the national strategic plan for Homeland Security science and technology.

The weapons of mass destruction medical countermeasures subcommittee provides an interagency forum for discussing and prioritizing medical countermeasure needs to be pursued under BioShield, and an HSC-led interagency biosurveillance committee provides a forum for coordinating and integrating the multiple activities in this area to provide an integrated biowarning and situational awareness system.

And then at other levels of coordination, there are strong bilateral efforts around key elements of the strategy. For example, examples include strong and frequent collaborations on BioShield with HHS, the development of a coordinated civilian and military surveillance and detection system with DOD, and the development and execution of a national strategy for agricultural biosecurity with the USDA.

The needs in three areas of this integrative biodefense have turned out to be so great to have generated Presidential initiatives. And there are three of them. These three initiatives are: BioShield, which we have already heard quite a bit about. One important point to make about that is that the S&T directorate played a sig-

nificant role in determining which agents constitute material threats and in developing the scenarios to inform decisions on the quantity of countermeasures required. We have certified one material threat, which is anthrax, have two additional underway, and three more are pending.

We also play a key role in the biosurveillance initiative in terms of first operating the biowatch system, deploying the second generation system to significantly expand the number of detectors in the highest threat cities and key facilities, and in developing advanced detection systems.

And then in addition, the S&T directorate is bringing significant contributions and end-to-end studies of key agricultural and food threats through the development of advanced diagnostics and through R&D conducted jointly with USDA at Plum Island Animal Disease Center.

Thus, the science and technology programs conducted within the Department of Homeland Security fully support the national biodefense program as stated in HSPD–10 and other Homeland Security Presidential directives. Moreover, they are conducted in an act of collaboration with other Federal departments and agencies having a role in meeting this national priority, and are focused on reducing the threat of a biological attack against the Nation's population and its agricultural and food critical infrastructures, and supports a science-based forensics and attribution capability.

This concludes my prepared statement. With the committee's permission, I request that my formal statement be submitted for the record.

Mr. Chairman, Congressman Turner, and members of the committee, I thank you for the opportunity to appear before you today and look forward to your questions.

Chairman COX. Thank you, Secretary Albright. Your written statement has been entered into the record.

[The statement of Dr. Albright follows:]

PREPARED OPENING STATEMENT OF DR. PENROSE C. ALBRIGHT

Good afternoon Chairman Cox, Congressman Turner, and distinguished members of the Committee. I am pleased to appear before you today to discuss the progress the Science and Technology Directorate of the Department of Homeland Security is making in the nation's efforts to prevent, protect against, respond to, and recover from, acts of bioterrorism against the American people.

President Bush has made strengthening the nation's defenses against biological weapons a critical national priority. Although significant progress has been made to protect America, President Bush instructed Federal departments and agencies to review their efforts and find better ways to secure America from bioattacks.

This review resulted in a joint Homeland Security Presidential Directive (HSPD–10)/National Security Presidential Directive (NSPD–33) entitled *Biodefense for the 21st Century.* that provides a comprehensive framework for our nation's biodefense. This directive builds upon past accomplishments, specifies roles and responsibilities, and integrates the programs and efforts of various communities—national security, medical, public health, intelligence, diplomatic, agricultural and law enforcement—into a sustained and focused effort against biological weapons threats.

The Department of Homeland Security (DHS) and the Science and Technology (S&T) Directorate have explicit responsibilities in this integrated national effort. In particular, I want to highlight the strategy, planning and accomplishments to date of S&T in the area of biodefense, and the essential collaborations with key Federal partners, including those represented here today.

BIODEFENSE

Before I speak directly to the biodefense efforts of the S&T Directorate, I want to briefly address the role of the DHS's Information Analysis and Infrastructure Protection Directorate, and how their work is linked to the S&T Directorate. The Information Analysis and Infrastructure Protection (IAIP) Directorate assesses intelligence and information about threats and vulnerabilities from other agencies and takes preventative and protective action. They are partners in the total interagency efforts to obtain, assess and disseminate information regarding potential threats to America from terrorist actions. These threat and vulnerability assessments are inputs into the strategy and research, development, testing and evaluation (RDT&E) activities of the Science and Technology Directorate. For example, agriculture and food are two of the multiple critical infrastructure sectors identified by Homeland Security Presidential Directive 7.As such, they fall within the domain of the IAIP Directorate; they also are within the domain of concern for biological threats.

Mission and Objectives:

The presidential directive *Biodefense for the 21st Century* outlines four essential pillars of the nation's biodefense program and provides specific directives to further strengthen the significant gains put in place in the past three years. Specific direction to departments and agencies to conduct this biodefense program is contained in a classified version of the directive and is not provided in the present document. However, the four pillars of the program are:

- **Threat Awareness,** which includes biological weapons-related intelligence, vulnerability assessments, and anticipation of future threats. New initiatives will improve our ability to collect, analyze, and disseminate intelligence on biological weapons and their potential users.
- **Prevention and Protection,** which includes interdiction and critical infrastructure protection. New initiatives will improve our ability to detect, interdict, and seize weapons technologies and materials to disrupt the proliferation trade, and to pursue proliferators through strengthened law enforcement cooperation, including through such mechanisms as Interpol.
- **Surveillance and Detection,** which includes attack warning and attribution. New initiatives will further strengthen the biosurveillance capabilities being put in place in fiscal year 2005.
- Response and Recovery, which includes response planning, mass casualty care, risk communication, medical countermeasures, and decontamination. New initiatives will strengthen our ability to provide mass casualty care and to decontaminate the site of an attack.

The Department of Homeland Security has a role and responsibility in each of these four pillars of the national biodefense program. The S&T Directorate has the responsibility to lead the Department's RDT&E activities to support the national biodefense objectives and the Department's mission.

Accomplishments and Planned Activities:

Dr. Charles E. McQueary, Under Secretary for Science and Technology, has previously testified before the U.S. House of Representatives, Appropriations Subcommittee on Homeland Security; the U.S. House of Representatives, Subcommittee on Cybersecurity, Science, and Research and Development; and the U.S. House of Representatives, Science Committee. The accomplishments to date and planned activities for FY 2005 of the Science and Technology Directorate and its RDT&E related to biological threats have been described in the written testimony for the record for those hearings and I will not repeat here the details already provided in those fora. However, there are some specific accomplishments and planned activities I want to describe because they illustrate the integrated efforts within the Department of Homeland Security and other Federal departments and agencies.

The Science and Technology Directorate contributes to each of the key areas of the national biodefense program. Our contributions and planned activities include:

- The S&T Directorate is funding a continuing all-WMD assessment effort. The program focuses on determining the capabilities of state and non-state terrorist groups to develop and deliver or deploy any chemical/biological/radiological/nuclear/explosives (CBRNE) agent within the United States. This work is being performed for IAIP; and the first reports, describing the capabilities of 20 Tier 0 and Tier 1 groups in biological, chemical, radiological, nuclear, cyber, and advanced explosives (or energetics) threat areas, have already been completed and delivered to IAIP. Furthermore, the S&T Directorate is in the process of embedding a team of WMD scientific experts to provide technical assistance to IAIP analysts and is installing a pilot Knowledge Information Tool, which enables access to the reports and all of the supporting data and information. .

- The S&T Directorate has established the National Biodefense Analysis and Countermeasures Center (NBACC), with the missions of threat characterization, forensics and attribution, and bio-knowledge. In order to fulfill these missions, the NBACC is comprised of three centers: the Bio Threat Characterization Center (BTCC), the National BioForensics Center (NBFAC) and the Biosecurity Knowledge Center (BKC). These components will provide a scientific basis to understanding the biological threat and become part of a data and telecommunications network enabling information sharing and threat and vulnerability analysis among a diverse set of users.
- The S&T Directorate is coordinating with the Departments of Defense, Health and Human Services, and Agriculture to establish the proposed National Interagency Biodefense Campus at Ft. Detrick. The NBACC is proposed to include the BTCC, focusing on threat characterization, and NBFAC, which provides interagency forensic capability. The synergy at this center will allow for integrated biodefense research programs across the government, better address the priorities established in the President's directive and provide scientific rigor to threat and vulnerability assessments for IAIP.
- The S&T Directorate has developed and implemented a Threat-Vulnerability Integration System prototype at IAIP. That system provides advanced information discovery, analysis, and visualization tools to IAIP analysts and will be used in concert with the Threat-Vulnerability Mapping System. Such advanced tools can be applied to the biodefense problem specifically or all-WMD analysis in general. To ensure use of these systems is optimized, the S&T Directorate has detailed technical personnel to IAIP.

The S&T Directorate addresses the full range of biological threats, but the initial emphasis in on active defense against high consequence threats- those that can inflict damage which would significantly challenge this Nation's immediate ability to respond, i.e. thousands or tens of thousands of serious casualties and/or economic losses in the tens of billions of dollars or higher. Such threats include large outdoor and indoor aerosolized releases of non-contagious and contagious pathogens, contamination of selected bulk food supplies, foreign animal diseases, highly virulent plant diseases, engineered threats, multiple small attacks, and zoonotic diseases.

In addressing these activities, the S&T Directorate has a leadership role in several key areas and partners with lead agencies in others. Those areas in which DHS provides significant leadership are:

- Providing an overall end-to-end understanding of an integrated biodefense, so as to guide the Secretary and the rest of the Department in its responsibility to coordinate the Nation's efforts to deter, detect, and response to biological acts of terrorism
- Providing scientific support to the intelligence community and IAIP in prioritizing the bio-threats
- Developing early warning and detection systems to permit timely response to mitigate the consequence of a biological attack
- Conducting technical forensics to analyze and interpret materials recovered from an attack to support attribution
- Operation of the Plum Island Animal Disease Center to support both research and development (R&D) and operational response to foreign animal diseases such as foot and mouth disease.

DHS also supports our partnering departments and agencies with their leads in other key areas of an integrated biodefense: the Department of Health and Human Services (HHS) on medical countermeasures and mass casualty response; the U.S. Department of Agriculture (USDA) on agriculture; USDA and HHS on food security and the Environmental Protection Agency (EPA) on decontamination and on water security.

Interagency Collaboration:

The previously mentioned presidential directive **Biodefense for the 21st Century,** as well as other Homeland Security Presidential Directives (HSPDs) including HSPD–9, Defense of United States Agriculture and Food; HSPD–8, National Preparedness; HSPD–4, National Strategy to Combat Weapons of Mass Destruction; and HSPD–7, Critical Infrastructure Identification, Prioritization, and Protection, identifies national objectives and priorities, and departmental and agencies? roles in addressing these national objectives.

The S&T Directorate has been, and continues to be an active participant in these interagency activities as illustrated by our participation in the biodefense program. At the highest level, the joint National Security Council-Homeland Security Council (NSC–HSC) Biodefense End-to-End Study and the ensuing HSPD–10/NSPD–33 (Biodefense for the 21st Century) laid out the overall strategy, department and

agency roles, as well as specific objectives and called for periodic reviews to plan, monitor and revise implementation. This was followed by an interagency review, conducted under the aegis of the NSC–HSC, of specific FY 2006–FY 2010 science and technology needs to support the national biodefense strategy as articulated in HSPD–10. This and other inputs such as those from the Counterproliferation Technology Coordination Committee (CTCC), the National Science and Technology Council's Weapons of Mass Destruction Medical Countermeasures Committee (WMD–MCM) and its associated subcommittees, and HHS—led risk management meetings which help guide medical countermeasures procurement activities are being documented in the *National Strategic Plan for Homeland Security Science and Technology* as required in the Homeland Security Act of 2002.

The Weapons of Mass Destruction Medical Countermeasures Subcommittee (WMD–MCM) provides an interagency forum for discussing and prioritizing medical countermeasure needs to be pursued under BioShield and an HSC led interagency Biosurveillance Committee provides a forum for coordinating and integrating the multiple activities in this area to provide an integrated biowarning and situational awareness system. At still the next level of coordination, there are strong bilateral efforts around key elements of the strategy. Examples of this coordination including strong and frequent collaborations on Bioshield (HHS/DHS), the development of coordinated civilian and military surveillance and detection systems (DHS/DoD) and the development and execution of a National Strategy for Agricultural Biosecurity (DHS/USDA).

Presidential Initiatives:

The needs in three areas of this integrated biodefense turned out to be so great as to have generated Presidential Initiatives to address them. These three initiatives are:

BioShield: which seeks to speed development and use of new biomedical countermeasures by creating a guaranteed market for these 'orphan drugs' and removing some of the barriers to their development and emergency use. DHS's S&T Directorate plays a significant role in this in determining which agents constitute "material threats" and in developing scenarios that inform decisions on the quantity of countermeasures required. We have certified one "material threat" (anthrax), have two additional underway, and three more are pending.

Biosurveillance Initiative: which seeks to enhance systems that monitor the Nation's health (human, animal and plant) and its environment (air, food, water) and to integrate these with intelligence data to provide early detection of an attack and the situational understanding needed to guide an effective response. The S&T Directorate plays a major role in the Biosurveillance Initiative in operating its 1st Generation BioWatch System, in deploying a 2nd Generation system which significantly expands the number of collectors in the highest threat cities and at key facilities (e.g. transportation systems), and in developing advanced detection systems to further increase the capabilities. We are also designing the information system that will be use to integrate health and environmental monitoring information from the sector specific agencies with intelligence data from the IAIP Directorate. Implementation of this system will actually be initiated by the IAIP Directorate in FY 2005, but the S&T Directorate will continue to supply subject matter expertise in biological threat and defense.

Food and Agricultural Initiative: which seeks to enhance the security of our agricultural and food infrastructures. DHS activities in this area are led by the IAIP Directorate—but the S&T Directorate brings significant contributions in end-to-end studies of key agricultural and food threats, through the development of advanced diagnostics, and through R&D conducted jointly with USDA at the Plum Island Animal Disease Center.

CONCLUSION

The Science and Technology Directorate's programs conducted within the Department of Homeland Security fully support the national biodefense program as stated in the presidential directive *Biodefense for the 21st Century,* and other Homeland Security Presidential Directives. Moreover, they are conducted in an active collaboration with other Federal departments and agencies having a role in meeting this national priority, and are focused on reducing the threat of a biological attack against this nation's population and its agriculture and food critical infrastructures, and supports a science-based forensics and attribution capability.

This concludes my prepared statement. With the Committee's permission, I request my formal statement be submitted for the record. Mr. Chairman, Congressman Turner, and Members of the Committee, I thank you for the opportunity to appear before you and I will be happy to answer any questions that you may have.

Chairman COX. Our next witness is Major General Lester Martinez-Lopez, commanding general, U.S. Army Medical Research and Materiel Command, at Fort Detrick, Maryland. Your written statement will also be entered into the record, and we welcome your oral testimony. General, welcome.

STATEMENT OF MAJOR GENERAL LESTER MARTINEZ-LOPEZ

General MARTINEZ-LOPEZ. Mr. Chairman, distinguished members of the committee, thank you for the opportunity to briefly discuss the national interagency biodefense campus that is being planned at Fort Detrick, Maryland.

As commanding general of the United States Army Medical Research and Materiel Command as Fort Detrick, I am responsible for delivering the best medical solutions for today and tomorrow to enhance, protect, and treat the warfighter on point for the Nation. This responsibility includes the protection against biological weapons.

Today, Fort Detrick is embarking upon a vision to become the home of the national interagency biodefense campus.

As the anthrax attacks demonstrated, the new biothreat respects no borders and knows no boundaries. Our homeland is at continual risk. After the attacks, many turned to Fort Detrick for answers because throughout its history, Fort Detrick has contributed scientific breakthroughs and medical solutions for their Armed Forces and the Nation. With Fort Detrick's United States Army Medical Research Institute of Infectious Diseases, expertise has a cornerstone, and in partnership with the National Institute of Health, the Department of Homeland Security, and the Department of Agriculture, I believe the National Interagency Biodefense Campus will be the Nation's primary center for development of defenses against biological terrorist attacks. These four agencies, complementary facilities, programs, and expertise in the context of the national biodefense campus will comprise the cycle of discovery for the badly needed medical solutions against this biothreat.

To take this campus concept from a vision to a reality, senior leaders from participating Federal agencies met in late May 2002. We developed a strategy, established combined facility working groups, and explore areas of research collaboration. One month later, the National Biodefense Interagency Coordinated Committee was established. This interagency work led to the completion of the National Interagency Biodefense Campus master plan. With your help, the National Institute of Food Allergies and Infectious Diseases will break ground for its new facility this year. The National Biosecurity Analysis and Countermeasures Center, NBACC, of the Department of Homeland Security, will shortly follow, and, as you may know, the Department of Agriculture planned pathogen laboratory is already at the Fort Detrick campus.

Let me share with you what each of these partnering organizations will bring to the table. For 34 years, USAMRMC has safely handled the world's deadliest pathogens and is home to most of the Nation's experts in infectious aerosol as well as biological threats. These world-renowned professionals have also crossed the globe to investigate or support infectious disease outbreaks and have provided training in how to respond to incidents. The USAMRMC

Building itself has an aerobiology lab, biosafety labs two, three, and four, and has the only biosafety level four patient care suite in the Nation.

The National Institute of Allergies and Infectious Diseases brings incredible expertise and resources from their previous efforts to understand, treat, and ultimately prevent a myriad of infectious immunologic and allergic diseases that threaten hundreds of millions of people worldwide. The Department of Homeland Security will establish a center that will conduct research to better understand classical as well as new and emerging biological threats to humans, plants, and animals. And in support of the FBI and other Federal agencies, a second center will provide validated authoritative forensic analysis.

Finally, the Fort Detrick's foreign disease with science research unit of the United States Department of Agriculture will continue its work on pathogen detection and identification of crop protection. In addition, the National Cancer Institute already has a large campus at Fort Detrick. Although their mission is direct research aimed at identifying the causes and treatment for cancer, their facilities and scientific expertise will complement and augment the biodefense campus work. The campus will mass research facilities, knowledge and expertise, creating a brain trust of civilian and military scientists in a way that will minimize duplication of effort, technology and facilities, while identifying ways to improve the ability of the labs to produce science, technology, and products that are faster, better, and cheaper.

The campus will share a common infrastructure and support requirements, such as roadways, libraries, cafeteria, regulatory and quality assurance offices, and will share securities, biosafety, and biosurety responsibility. We are also looking at cost saving mechanisms such as enhanced use lease for a central utility plan. We are making real progress every day toward division of the national interagency biodefense campus at Fort Detrick, and will be—which that will be a collaborative center of excellence for our Nation. All partners have established good working relationships, and the community is supportive. I am excited to be part of this bright future.

Mr. Chairman, this concludes my remarks, and I will be pleased to answer your questions.

Chairman COX. Thank you, General.

Chairman COX. Our next witness is Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, the Department of Health and Human Services, NIH. Thank you, Dr. Fauci. Welcome back.

STATEMENT OF DR. ANTHONY FAUCI

Dr. FAUCI. Thank you very much, Chairman Cox, Mr. Turner, members of the committee, I appreciate the opportunity to again appear before you as I did about this time last year.

I was asked by committee staff to briefly address three areas of the NIH research response to the threat of bioterrorism. And those are a summary, which I will give shortly, of the biodefense research activities, how we coordinate these research activities among agencies, and, finally, how the research and development priorities are based on threat assessment.

Chairman COX. Dr. Fauci, if you would suspend just for a moment. We have had two bells indicating that there is a vote on the floor. I would propose that we go forward with your oral testimony. And Dr. Raub, we will recognize you, but my understanding is that you do not have a formal statement. That will permit members to return following floor votes to begin questioning the panel. So I want members to be alert to remain for the formal testimony. And Dr. Fauci, I want you to not be bothered by the buzzers that probably will continue to interrupt your testimony.

Dr. FAUCI. Will do.

Chairman COX. Please proceed.

Dr. FAUCI. At your pleasure. Okay. Next slide.

Again, just historically, as referred to by you and Mr. Turner, about a year ago when I discussed with this committee the strategic plan that we had brought up in response to being able to execute the mandate of doing the research necessary to develop appropriate countermeasures for biodefense threats, we put together a strategic plan, which I briefly outlined for you at the time, and also we put together a research agenda for Category A, and Category B and C agents.

Since that time, we have now put together a progress report on both of those. And I would recommend to you and your staff, if you get the opportunity, to page through those. It is available on the Web, in which we outline not only the accomplishments that have occurred since that time, but also a supplementation of where we will be going in the future. So let me briefly outline some of that for you.

The first that I alluded to last year was the need for building up both our human capital and our physical infrastructure to be able to do the research necessary to develop these countermeasures. Since that time, significant progress has been made. We now have the funding that has been disbursed for the development of two national biocontainment laboratories or BSL–4s, one in Texas and one in Boston; nine additional regional biocontainment laboratories, or BSL–3s. And, importantly, again, I discussed with the committee last year the need to get the best and the brightest of the infectious diseases, microbiology, and immunology scientific community involved in the biodefense effort. By the awarding of our regional centers of excellence for biodefense and emerging infectious diseases, eight in number, in fact, I believe we have succeeded in that, because we have the best of our established and now younger people coming into the field.

And, finally, there have been four new facilities that are government-owned, one going up right now in construction on the NIH campus, a BSL–3. Dr. Martinez-Lopez referred to the BSL–4 that we are going to be collaborating with on the campus in Fort Detrick as well as the BSL–3 in Rockville and the BSL–4 in the Rocky Mountain Laboratories in Hamilton, Montana.

What about the research? I put the slide together to show you the continuum of the fundamental basic research in concept development of which we have been quite successful. I will give you some examples, but I will be happy to discuss this during the questioning period. In addition, several products already have gone from the preclinical and the animal model up through phase one

and into phase two, and right now we are pushing the envelope as we promised towards the development of these three types of products, diagnostics, therapeutics, and vaccine. And as you know, as we discussed last time, it is at this point where Project BioShield will kick in.

What about these countermeasure developments? Significant progress has been made in smallpox, the development of a safer, not reactogenic smallpox vaccine. In other words, the Modified Vaccinia Ankara that I mentioned to you, we had to prove that it was effective in animals at the same time we are proving it is safe in humans. Both of those things have gone on. A couple studies have been completed. We have shown in a monkey model and in a mouse model that it protects these animals from challenge with either smallpox or its equivalent. And this is an important issue with regard to the FDA's "two animal rule" for approval.

With regard to anthrax, we are well into the clinical trials of the recombinant protective antigen, contracts have been let, and we are on our way to getting that into the stockpile.

Also, since we spoke last, we now have an Ebola vaccine that protects monkeys that is now in a phase one clinical trial in humans started on the NIH campus in November of 2003. We also made advances in therapeutics. We are testing a therapeutic against smallpox as well as, based on the pathophysiology of anthrax, ways in which we can block the actual toxin. We know we have very good antibiotics against anthrax, we know we can block the toxin in people with advanced diseases, and some in-roads that have been made in diagnostics in the arena of smallpox as well as anthrax.

Let me briefly address the question regarding coordination of biodefense activities. There are three levels. At the NIH, as you are aware, the NIAID is by far the lead institute in executing the research in bioterror agents. But there are other institutes that are involved also at NIH, and I chair a committee that is called the NIH Biodefense Research Coordinating Committee, in which we coordinate among the NIH institutes.

At the level of the Department, the coordination falls under the auspices of the Office of the Assistant Secretary for Public Health Emergency Preparedness, where the NIH, the FDA, and the CDC are coordinated. And at the Federal Government level, it is coordinated at the White House by the Homeland Security Council and the National Security Council. And these are the Federal agencies involved. Predominantly, DHS, HHS, and DOD, which are represented here at this hearing, as well as other relevant agencies.

And, finally, the question was asked: How do we establish the research and development priorities based on threat assessment? The first was the CDC category A, B, and C agent designation, which we have made the foundation for the research direction that we put into our original strategic plan. Right now, currently the Department of Homeland Security has taken the lead in providing us with continual threat assessments, and we rely heavily on the Department to work with us in a collaborative way so that we can direct our research toward the appropriate groups. That is my formal statement, Mr. Chairman. I would be happy to answer questions later.

Chairman COX. Thank you, Dr. Fauci.
[The statement of Dr. Fauci follows:]

THE NIH BIOMEDICAL RESEARCH RESPONSE TO THE THREAT OF BIOTERRORISM

PREPARED STATEMENT OF ANTHONY S. FAUCI, M.D

Mr. Chairman and Members of the Committee, thank you for the opportunity to speak with you today about the role of the National Institutes of Health (NIH) in the execution of our national biodefense research strategy.

The destruction of the World Trade Center, the attacks on the Pentagon and an airliner over Pennsylvania, and the anthrax attacks in the fall of 2001 clearly exposed the vulnerability of the United States to acts of terrorism. In particular, the anthrax attacks made it very clear that the possibility of the use by terrorists of deadly pathogens or biological toxins such as those that cause anthrax, smallpox or botulism represents a serious threat to our Nation and the world. The Administration and Congress responded aggressively to this threat by significantly increasing funding for biodefense preparedness and research.

The National Institute of Allergy and Infectious Diseases (NIAID) is a component of NIH and a leading federal agency for biomedical research concerning potential agents of bioterrorism that directly affect human health. NIH, and particularly NIAID, has devoted the increased biodefense research funding to an aggressive, broadly based research program designed to provide the American people with medical countermeasures, i.e. vaccines, therapeutics, and diagnostics against a range of bioterrorist threats. My remarks today will specifically address three aspects of our biodefense research activities. I will first describe the NIH biodefense research program, including a few examples of our recent accomplishments. Next, I will summarize how NIH biodefense research is coordinated with research carried out by other Federal agencies. I will close by discussing how NIH is informed about and responds to new bioterror threats that might arise.

NIH Biodefense Research

The NIH research agenda for defense against bioterrorism was developed through a comprehensive and systematic strategic planning process. In February 2002, we convened the Blue Ribbon Panel on Bioterrorism and Its Implications for Biomedical Research, with membership composed of distinguished researchers from academic centers, private industry, government civilian agencies, and the military. Three key documents were developed based on this panel's advice and on extensive discussions with other Federal agencies: the *NIAID Strategic Plan for Biodefense Research, the NIAID Research Agenda for CDC Category A Agents* (for those agents that pose the gravest threat), and the *NIAID Research Agenda for CDC Category B and C Agents* (agents whose biological properties make them more difficult to deploy or less likely to cause widespread harm). The Strategic Plan provides a blueprint for the conduct of basic research on microbes and host immune defenses, as well as targeted, milestone-driven development of drugs, vaccines, diagnostics and other interventions that would be needed in the event of a bioterror attack. The two biodefense research agendas describe short-term, intermediate, and long-term goals for research on the wide variety of agents that could be used to conduct such an attack.

NIH has moved rapidly to execute its biodefense strategic plan and significant progress toward reaching many of the goals set forth in the research agendas has already been made, as described in two recent progress reports. With regard to basic research, which is needed to understand more about how pathogens interact with human hosts, NIAID-supported researchers and their international colleagues have completely sequenced the genomes of representative bacteria considered to be bioterror threats, including multiple strains of the anthrax bacterium, as well as at least one strain of every potential viral and protozoan bioterror pathogen. Another NIAID program is supporting studies of the human innate immune system, which is comprised of broadly active "first responder" cells and other non-specific mechanisms that are the first line of defense against infection. The development of methods to boost innate immune responses could lead to fast-acting countermeasures to mitigate the effects of a wide variety of bioterror pathogens or toxins; in addition, manipulation of the innate immune system could lead the way towards the development of powerful adjuvants that can be used to increase the potency and effectiveness of vaccines.

NIH also has moved aggressively to expand national biodefense research capabilities by investing in several research infrastructure development programs, including manpower and facilities. For example, NIAID recently funded eight Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research. This

nationwide network of multidisciplinary academic centers will conduct wide-ranging research on infectious diseases that could be used in bioterrorism, and will develop diagnostics, therapeutics and vaccines needed for biodefense. In addition, these Centers will serve as the training ground for future generations of biodefense researchers. The Centers also partner with State and local public health agencies to ensure the strongest coordinated response to a bioterrorist event. In addition, NIAID is supporting the construction of two National Biocontainment Laboratories (NBLs), which will include facilities built to Biosafety Level 4 standards and will therefore be capable of safely containing any pathogen, as well as nine Regional Biocontainment Laboratories (RBLs) with Biosafety Level 3 facilities. These high-level research laboratories will provide the secure space needed to carry out the nation's expanded biodefense research program in a setting of safety for both biodefense workers and the surrounding community. Other ongoing projects will expand intramural facilities at Bethesda and Rockville, Maryland, at our Rocky Mountain Laboratories in Hamilton, Montana, and in Frederick, Maryland.

The ultimate goal of all NIH biodefense research is the creation of new and effective medical countermeasures, including vaccines, therapeutics, and diagnostics against potential bioterror agents. Substantial progress toward this goal has already been achieved. In the area of therapeutics, for example, NIAID-supported scientists have identified a drug that may prove useful in treating both smallpox and the complications of smallpox vaccination. This agent, called cidofovir, is approved by the FDA for treating viral eye infections in HIV-infected patients. NIAID studies also are investigating the use of antibodies that can bind to and block the action of toxins produced by the anthrax bacterium, as well as botulinum toxin.

New and improved strategies for the development of vaccines against smallpox, anthrax and other potential bioterror agents are being vigorously pursued, with the objective of adding them to the Strategic National Stockpile (SNS) as quickly as possible. For example, NIAID is supporting and overseeing the rapid development of the next-generation anthrax vaccine known as recombinant protective antigen, or rPA. Clinical trials of rPA are ongoing; results to date build on findings in animal studies that suggest the vaccine is safe and capable of evoking a robust immune response. Researchers also will test, in animals, whether protection against anthrax can be enhanced by receiving the rPA vaccine in addition to antibiotic therapy following exposure to anthrax spores. This development effort is on track for Project BioShield to award contracts this year to achieve the goal of adding 75 million doses of rPA vaccine to the SNS to protect 25 million U.S. citizens.

NIAID-supported researchers also are testing several new smallpox vaccines that may prove at least as effective as the current smallpox vaccine, and can be used by a broader population, including those who are immunocompromised. One of these, modified vaccinia Ankara (MVA), is based on a strain of the vaccinia virus that replicates less robustly than the traditional Dryvax vaccinia virus, and which is also known to cause fewer side effects. Human trials of MVA vaccines are under way at NIH and elsewhere. Encouragingly, recent studies by NIAID intramural scientists and their colleagues have shown that MVA protects monkeys and mice from smallpox-like viruses. NIH also has launched the first human trial of a vaccine designed to prevent infection with Ebola virus. The trial vaccine is made from parts of the viral DNA, and is similar in design to other investigational vaccines that hold promise for controlling such diseases as AIDS, SARS, and infection with West Nile virus.

Coordination of Biodefense Research

Although NIH is a leading agency in government-sponsored biomedical biodefense research on agents that directly affect humans, it is by no means the only agency involved; the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), the Department of Homeland Security (DHS), the Department of Agriculture (USDA), and other governmental organizations also play important roles. Coordination among the various agencies involved is therefore extremely important. In broad terms, the NIH biodefense research agenda and activities are coordinated at three distinct levels: within NIH, within DHHS, and across the government as a whole.

Within NIH, NIAID is responsible for the bulk of NIH-sponsored biodefense research; other NIH institutes, however, also make significant contributions. The focal point for trans–NIH coordination and planning of biodefense activities is the NIH Biodefense Research Coordinating Committee. I am Chairman of this committee, which meets at least quarterly or more often, as needed. It is administered by the NIAID Office of Biodefense Research, which also serves as liaison office for NIH contacts with other federal agencies such as DoD and DHS regarding biodefense research and response.

At the level of the Department of Health and Human Services (DHHS), coordination of biodefense research between the CDC, NIH, FDA and other agencies within DHHS is the responsibility of the DHHS Office of the Assistant Secretary for Public Health Emergency Preparedness (ASPHEP). The ASPHEP Office of Research and Development Coordination holds periodic meetings with all governmental stakeholders in the development of medical countermeasures.

Members of my staff also meet regularly with the research community at Fort Detrick and the U.S. Army Medical Research and Material Command. Through such meetings, synergy in research and mutual support leading to the development of new drugs, vaccines, and diagnostic tests for the nation are achieved. My staff also holds meetings periodically with the Defense Threat Reduction Agency and the Defense Advanced Research Projects Agency, two important entities within the research infrastructure in the DoD.

At the highest level, coordination of biodefense research is carried out by the White House, and in particular the Homeland Security Council, now led by Frances Townsend, and the National Security Council. In addition, the Committee on Homeland and National Security of the National Science and Technology Advisory Council also participates, especially through its Weapons of Mass Destruction Medical Countermeasures Subcommittee.

Although these three levels describe the basic structure through which the Nation's biodefense research programs are formally coordinated, NIH, as the lead biodefense research agency, collaborates daily with the other federal agencies and is party to a large number of interagency programs, informal contacts, and communication mechanisms that significantly contribute to the efficiency and effectiveness with which biodefense research is carried out across the U.S. government.

Threat Assessment and the Research Response

We developed the *NIAID Strategic Plan for Biodefense Research* and the two research agendas based on an overall threat assessment formulated by CDC in close cooperation with the intelligence community. Category A agents are the most dangerous microbes and toxins; these include anthrax, smallpox, plague, botulism, tularemia, and hemorrhagic fevers caused by viruses such as Ebola. These agents were given the highest priority because they a) are relatively easily disseminated or transmitted from person to person; b) result in high mortality rates with the potential for major public health impact; c) would likely cause significant social disruption; and d) require special action for public health preparedness. Category B agents are in the second tier of priority. They are agents that a) are moderately easy to disseminate, b) result in moderate morbidity and low mortality rate, and c) require specific enhancements of national diagnostic capacity and disease surveillance systems. Category C Agents have the next highest priority. They include emerging pathogens that could be engineered for mass dissemination in the future because of their availability, ease of production and dissemination, and potential for high morbidity and mortality rates and major health impact.

To receive information about new threats that may arise, we work closely with DHS, which provides threat assessments concerning issues germane to our research. Because new infectious disease challenges emerge naturally on a regular basis, NIH has considerable experience in rapidly mobilizing research resources to confront new infectious disease threats. This experience serves us well when called upon to adjust our research priorities in response to new intelligence information.

In closing, I am confident that the biomedical research agenda we have formulated concerning potential agents of bioterrorism is well conceived, and will rapidly lead to new and improved medical countermeasures against agents of bioterrorism. I am also very pleased with the degree of coordination and cooperation between NIH and other federal agencies involved in carrying out biodefense research.

I appreciate this opportunity to testify before you today, and I would be pleased to answer any questions that you may have.

Chairman COX. And I would like at this point to welcome our accompanying witness, Dr. William Raub, principal deputy assistant secretary for public health emergency preparedness at the Department of Health and Human Services. We understand that you will be available to take member questions as a member of this panel. Members are advised that there are two votes on the floor, a motion to construct conferees on the highway bill, and the Cox resolution concerning human rights in the Peoples Republic of China. All

members are encouraged to vote aye on that. We will return as quickly as we can upon the conclusion of votes on the floor.

[Recess.]

Chairman COX. Welcome back. Our members will be returning episodically from the floor. The committee is reconstituted.

I will begin with my questions for the panel by thanking you for your outstanding testimony and for being with us today on a very important topic. The Department of Homeland Security, Department of Health and Human Services, and the Department of Defense, as we just heard, are working together to establish a joint research facility at Fort Detrick, National Interagency Biodefense Campus.

For the record, may I ask which agency of the Federal Government is in charge of this?

Dr. ALBRIGHT. Can I take that? Okay.

Chairman COX. Whoever answers the question.

Dr. ALBRIGHT. Whoever goes first, I guess, gets the ticket. Yes, we are in charge. I think what the National Biodefense Campus is really aimed at doing is providing a venue where each agency that is operating within the confines of its running lanes, for example, the responsibilities that have been assigned to it by the national biodefense strategy, for example, can operate in a collaborative environment. So I think it's a mistake to say that any one person is in charge of the campus. So, for example, we are in charge of NBACC, Dr. Fauci has responsibilities for what NIAD is operating up there, and General Martinez-Lopez will be responsible for USAMRIID, and of course works within the U.S. Army for the facility that actually will house the site.

The idea behind the campus is that you have several groups of people at USAMRIID, at NBACC, and at NIAD who are addressing different aspects of the bioterrorism problem. And, therefore, it is important, and in our view, beneficial to have an environment where these people are eating together in the same cafeteria, their kids are in the same day care center, they are going to the same seminars, there are some potential shared assets such as animal facilities, for example, that you know can avoid duplication.

But, basically, when we talk about the Center, it is really aimed at promoting a professionally collaborative environment where, again, people who are working different parts of the problem can freely intermingle and share ideas.

Chairman COX. Is USAMRIID providing the technical staff to support the DHS capability, or is DHS providing its staff and only utilizing the laboratory space?

Dr. ALBRIGHT. What is happening right this second is we provide staff, but we are utilizing USAMRIID space. As you are well aware, we have a construction proposal in our 2004 and 2005 budget to actually build a building that would be right across the street from USAMRIID, but right now we are utilizing USAMRIID spaces.

Chairman COX. Perhaps then I should have asked if you could very succinctly summarize the roles of these three agencies in a sort of one-line mission statement.

Dr. ALBRIGHT. Okay. NBACC's primary—the Department of Homeland Security's primary function up there is threat characterization and assessment. NIAD, of course, conducts fundamental re-

search and development activities. USAMRIID does much of the same, but is focused on the warfighter. And I would invite—.

General MARTINEZ-LOPEZ. Mr. Chairman, if I may, also the Department of Agriculture is part of the partnership, and they bring about some of the knowledge on the crop pathogens which also can be—agroterrorism is part of the biothreat. And they are looking, and some of the technology and some of the basic science is very similar. So what we want to do is leverage all the knowledge from all the four partners, and also NCI. Even though, you know, the National Cancer Institute is really just looking at cancer and treatment and that kind of stuff, but they are developing vaccines against cancer, they are developing new basic science and understanding of how cells behave. And that knowledge is critical to us. And so having all that knowledge, all the—science still is about people, sir. I mean, science is not about technology, science is about great scientists that are doing the discovery and putting it in that context. So if you create the right environment for them to really collaborate and talk and share the knowledge, I think we can advance that much further.

Chairman COX. If there is no other comment on that, open opportunity to comment, then let me ask about NBACC, the National Biodefense Analysis and Countermeasure Center, which has been established within the S&T directorate to be the operationally focused technical biodefense analysis center within Homeland Security.

First, how is DHS organizing NBACC to fulfill this mission? Second, what is the gap in biodefense capabilities that NBACC is filling?

Dr. ALBRIGHT. I hope I can answer both those questions at the same time by telling you how we are organized. There are sort of two key capabilities that will be developed at NBACC. There is something called the National Bioforensics Analysis Center. This is a capability that we are doing jointly with the FBI. The original motivation for it was the fact that after the anthrax attacks, the FBI needed a place to do analysis on contaminated mailboxes and that sort of thing. So there was a need to have a national capability to analyze, to be able to hold and analyze evidence that is collected associated with bioterrorism, and ultimately to perform the appropriate analysis so that we can attribute the attack. And that of course is a very technical area that doesn't really exist in the Federal Government today, or it exists in a fairly disconnected way.

The second key capability is the biological threat characterization center. And what it will do is conduct laboratory experiments and studies to fill important gaps in our knowledge regarding the risks from specific high consequence pathogens. For example, one might be concerned about the reality behind certain emerging threats, engineered pathogens, for example. It is important to be able to do experiments to verify whether or not these pathogens in fact can be engineered without affecting their function. So, for example, one might be concerned about a particular threat and doing a genetic modification to it that increases its virulence in some manner. These are living organisms, after all, and you just don't fool around with the genes of these things without having impacts elsewhere.

It may be possible to do such a thing, but it also has an effect on its liability and nature, for example, or in your ability to weaponize it, or on a whole lot of other factors.

So a large part of what this center is intended to do is provide an environment where we can do sensitive work like that, to first analyze and understand what the potential emerging threats are. And that is, of course, an analytic effort. It is paper studies and that sort of thing. And then, if necessary, to understand the realities of those threats so that the people who generate the medical countermeasures at NIAD, for example, can respond appropriately.

Chairman COX. I thank you very much. My time has expired. I have other questions on biowatch, biosurveillance, basic research, and so on, and possibly I will get a chance to ask another round. But at this point, I yield to the Ranking Member, the gentleman from Texas, Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman.

Dr. Fauci, you know of my interest in trying to shorten the drug and vaccine development timetable. And I have also shared with you my concern, which I know you share, about the trends in the pharmaceutical industry away from production of antibiotics toward the more lifestyle drugs that are more profitable. Give me some sense of the kind of investments through your grant programs or internal activities, the degree and the amount of emphasis that we are placing on trying to shorten this drug development, vaccine development time frame, which I believe is so vital to dealing with the bioengineered threats that we know will be out there in the future.

Dr. FAUCI. Yes, thank you for the question, Mr. Turner. The issue of the development of new antibiotics, particularly antibiotics against drug-resistant microbes, is a threat that really transcends biodefense and is involved even in our natural interaction at the level of treating people at hospitals. The NIAID has a major investment in antibiotic development, particularly in the arena of antibiotic resistance to the tune of in fiscal 2005 an estimate of about 185, $187 million.

I look upon this in the same manner as we discussed on several occasions regarding other countermeasures, where there is a push and there is a pull. And the push is the amount of investment that you put into research to identify new targets. One of the things that we have invested in—and the biodefense research agenda has really enabled that—has been the ability to rapidly sequence microbes, things that took a year and a half years ago, now you can do in a day or two. And that allows you identify the various multiple targets of vulnerability for an antimicrobial.

So the investment in basic research allows us to do that. The problem that we face, as you yourself just mentioned, is that the companies that are involved in the actual making of that antibiotic have other fish to fry many times. They have other drugs to make that people will use for a lifetime as opposed to an antibiotic which most courses are 10 days to two weeks, and then you stop using it. Or, there is the development of resistance, which makes that antibiotic ultimately unusable.

Dr. FAUCI. We have also enhanced and made available our clinical trial networks to be able to have those companies use our net-

works to test drugs. What we don't have—and are working towards—is to develop the same sort of positive incentives for companies to get involved in an arena of development that is not intuitively profitable for them, and the ways that we have done that is to try and partner with them to give them the comfort that we will be with them in the long run. We will partner to try and push the process of research and development further towards the actual advanced development so that their risk in getting involved is somewhat decreased, around the same broad general philosophy of what we are trying to do with Project BioShield.

Mr. TURNER. How much would you say that we are investing today in that effort to push that issue forward in the same manner that—we obviously have made a tremendous investment and commitment financially in BioShield to take care of the end. How much are we investing right here in the middle where we need to, I think, make an investment and have, I hope, national commitment to get this done?

Dr. FAUCI. We are progressively now, over the last year and a half, putting a relatively larger proportion of that $185-some-odd million that we spend on antibiotic development to push into that. I can't give you a specific number except that when we do our projected planning of what the portfolio is going to look like, we are ever torquing more towards pushing it towards that development. So we don't have a number, but we are gradually being able to do that over the past year and a half to 2 years and will continue that in the future.

Mr. TURNER. So it seems we may have a little time to deal with this, but the uncertainty of it tells me that this is clearly an area where we need to stay out in front and on the cutting edge. And I don't know, General Martinez, if you can share with us if there is any similar effort going on within the Department of Defense to be able to do this. Do you have a parallel effort to the ones that Dr. Fauci refers to within DOD?

General MARTINEZ-LOPEZ. Sir, actually we do. But the good news is that we are in partnership with NIH. So the effort is a joint effort trying to—it is not compete the same industry—trying to foster the total industry forward. So from my view, I am talking more from the tactical level, but what I see is that there is really an effort in the Department, in the two Departments, to really advance this cause, and it is a concern to both of us.

Mr. TURNER. Thank you. I think my time is up.

Chairman COX. The gentleman from Connecticut, Mr. Shays, is recognized for, if I am not mistaken, 8 minutes.

Mr. SHAYS. Thank you very much, Mr. Chairman. And, gentlemen, welcome, and thank you for your service to our country.

I want to know how do you keep biodefense research and procurement in sync with the threat? I see four blank faces, and I am going to start with whoever wants to jump in. The question is how do you keep biodefense research and procurement in sync with the threat? The threat exists right now. I am hearing that some things will not be resolved for 9 years, and I want to know how we get it more in sync.

Dr. FAUCI. It is an iterative process of modifying your research direction, but there is a fundamental basic research endeavor that

really translates to any threat. Let me just give you an example. The example of the sequencing of virtually every microbe on the threat list, more than one strain of every microbe on the threat list. This allows us to respond to the possibility of there being a deliberate mutation, a deliberate genetic modification of that microbe. We have a given threat list. Sometimes a countermeasure will take years. We try to close that window as much as we possibly can, but we can't do the impossible. Sometimes things just take a couple of years. But if you look at the threat assessment that we had in front of this committee a year ago when we were talking about the vulnerabilities with smallpox, with Ebola and with anthrax and look a year later, I would say, Mr. Shays, that the amount of progress that has been made to close the gap of that threat is the fastest that I have ever seen in any public health endeavor.

And we continually reassess the threat assessment, as I mentioned in my opening statement, by our partnering with the Department of Homeland Security which keeps us reassessed of whether the threats are changing.

Mr. SHAYS. I would like to hear answers from others. Thank you for your answer.

Dr. ALBRIGHT. I guess I would make the same point Dr. Fauci made, and that is I think there is a fairly clear understanding of the threat, and as he pointed out we work closely with him as the threat evolves, but you cannot—to say it perhaps more succinctly, you can't command science, you can't deliver things instantly. So there is a certain amount of research that is required to develop countermeasures, and that just takes time to do.

Mr. SHAYS. Anyone else? The answer is the same?

General MARTINEZ-LOPEZ. Yes, sir.

Mr. SHAYS. The issue of botulitum antitoxin, how far are we away?

Dr. FAUCI. We have botulism antitoxin. We don't have enough for a massive attack. There are two avenues that are going on simultaneously. One are the stores that were actually under the purview of the Department of Defense of horse plasma that has been converted to—.

Mr. SHAYS. I am just curious to know how far are we to having the supplies that we need for a serious outbreak?

Dr. FAUCI. It would probably take—right now if there were an attack involving thousands of individuals, we have enough right now. If there is an attack that involves hundreds of thousands of individuals, we are probably a couple of years away from that.

Mr. SHAYS. More than 2 years certainly?

Dr. FAUCI. Yes.

Mr. SHAYS. Three, four, five?

Dr. FAUCI. I would say probably around 3 to 4 years away from that.

Mr. SHAYS. I had heard 9 years; so that is inaccurate?

Dr. FAUCI. Again, the question gets asked in multiple different way ways. It really depends if you are talking about enough to feel comfortable that in even the most massive threat, then you are talking 9 or 10 years or maybe even longer. If you are talking about expanding it to the point where we have a reasonable level

of comfort that even a modestly big attack you can go to, then I think you are talking 3 to 4 years.

Mr. SHAYS. Why aren't we on three shifts to deal with this issue? I mean, really, why aren't we on three shifts? Why is it going to take 2 to 3 years to basically deal with the threat? And I want to know why we aren't having people who work 24 hours a day, three shifts, just get it done? Is there an answer?

Dr. FAUCI. I think the answer is the reality of the situation of the prioritization of things that need to be done right now, given the manpower that is involved, given the resources we have, I think if we did that there might be a disproportional amount to a real threat, but one of many threats. So I would like to see—I mean, as someone who is involved in the research on this, I would have to say if I had my way, as it were, and you can never have your way all the time, I would have 24-hour shifts on everything.

Mr. SHAYS. But with all due respect, that is what your testimony should be. Your testimony should be before this committee, this is what we need. If we don't deliver, then it is our fault. If you don't tell us, then it is your fault. And I know you have a tremendous task, but I have had 50 hearings on the terrorist threat in my subcommittee, and I am surprised that we seem to think it is a 9-to-5 kind of effort, 2 to 3 years. If it is a serious outbreak, 4 to 5, maybe 9. It doesn't make me feel very comfortable.

One of the things that I am uncomfortable about is there is a lack of interagency cooperations and communications between DHS, DOD, HHS, CDC, NIH, as it relates to this issue of BioShield, and I want to know what is going to break through so we don't have people going in different directions. What does this committee need to do to force you to have better interaction?

Dr. ALBRIGHT. I guess I am not sure how much better we could interact than the way we do. We have multiple coordinating mechanisms that exist. For example, in BioShield in particular, there is—as the legislation was being proposed, the way that we set up a medical countermeasures working group with a number of activities designed around prioritizing and even developing procurement strategies for the various pathogens of interest. So, for example, I co-chair with HHS the procurements acquisition

Mr. SHAYS. Is it your testimony that you disagree and that there is very good coordination? Is that your testimony?

Dr. ALBRIGHT. Yes, it is.

Mr. SHAYS. Because we are going to have testimony that says that is not true.

Dr. ALBRIGHT. I would say there is excellent coordination. In fact, I see Tony at least once a month, I would say.

Mr. SHAYS. Is that a lot?

Dr. ALBRIGHT. For senior leadership to run into each other? Yes, sir, I would say so. I have people on my staff who interact with HHS on a daily basis.

Mr. SHAYS. Why does DOD, General Martinez-Lopez, pursue its own efforts, separate from HHS, that parallel; and why is it that DOD does not have to have the same regimen dealing with children and the elderly that we require from HHS?

General MARTINEZ-LOPEZ. Sir, let me see if I got the question right. When we develop a vaccine, are you saying that we don't have the same requirements for children?

Mr. SHAYS. Right.

General MARTINEZ-LOPEZ. We are trying to get the FDA approval, and if this is a strategy that is unique to the Department of Defense, that it is going to be only used for warfighters, then obviously the FDA may only license that product for an age group, both males and females. But quite often, like with—but right now as we move into the future, sir, many of the products, for example, the RPA, the next generation anthrax vaccine, one of our products has been—.

Mr. SHAYS. General, let me be clear, though. What you develop is not just for the military.

General MARTINEZ-LOPEZ. Correct.

Mr. SHAYS. And what makes me nervous is you don't follow the same regimen, and yet in the end what you do may be used for elderly and children.

General MARTINEZ-LOPEZ. The good news, sir, is right now, as an example, the RPA vaccine, that is a new generation anthrax vaccine, was developed initially by the Department of Defense. Now it is being followed by NIH, and when it is licensed it is going to be licensed for both, for general population. So this is an effort where the interagency—in the old days, the Department would have followed probably just a warfighter FDA licensing. Now we are going to be looking at a more general population licensing because the interagencies are working on those issues. There will be countermeasures that will be unique to the Department of Defense because their strategy may be different the way we approach a particular disease. In those cases I don't know how we are going to pursue that—.

Mr. SHAYS. I would thank you all for your service. I know you are trying to do the best you are doing. I just would conclude by saying when I hear 2 or 3 years, if there is an outbreak before, the question that is going to be asked of us is, why wasn't this an around-the-clock effort? And it isn't. And that is what of concern.

Thank you, Mr. Chairman.

Chairman COX. The gentleman's time is expired.

The gentlelady from the Virgin Islands, Dr. Christensen, is recognized for 8 minutes.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. And welcome to the panelists.

I share some of those concerns, and when other areas' directors, agencies, come before this committee, we are always very concerned with, one, the slow pace of the readiness and preparedness, the often lack of clear lines of responsibility and the lack of institutionalized coordination. We hear about coordination that takes place, but it seems to be very informal and dependent on the people in place, and we would like to see that more concretized so we know that it will continue regardless of who is there and who is working in these areas.

Dr. Fauci, I promised you a question, because we have gotten into this before, during the BioShield hearings. Do you have any indication from within the Department that the same emphasis

that is being placed on research is being put in the public health preparedness and any thoughts on just how effective all of this wonderful research can be and the wonderful counteragents deployed and utilized when they are needed, if our public health infrastructure, the facilities, the staff, the training, is not adequate and in place?

Dr. FAUCI. Mrs. Christensen, I could answer the research part, but I would have to ask Dr. Raub to answer the public health preparedness, because that is not something I am responsible for. The research is going at a very rapid rate and I might, if you would allow me to, just comment about what was just said by yourself, saying the slowness of the pace and what Mr. Shays mentioned about—.

Mrs. CHRISTENSEN. Coordination.

Dr. FAUCI. How can we increase this pace.

Mrs. CHRISTENSEN. Not too long, though.

Dr. FAUCI. No. It is going to be real short. When you are doing research, there are things you can't push because the science doesn't go to your demand. And that is something that really needs to be understood. You can't demand the science to give you a discovery.

The other thing is that even when you are making a product, for example, botulism antitoxin, there are two ways to make it. You vaccinate a horse or you try to develop a monoclonal antibody. A monoclonal antibody takes years to develop and to develop correctly. You vaccinate a horse, it takes 3 to 4 months before the next boost, another 4 to 5 months before the next boost, and another 4 to 5 months before the next boost before you get a titer even high enough to bleed the horse. So you could stand there and watch that horse 24 hours a day, but it is not going to have that horse make antibodies anymore quickly. So there are constraints that we have.

Mrs. CHRISTENSEN. I will come back to that, too. But go ahead, Dr. Raub, please.

Mr. Raub. Thank you. The emphasis on strengthening State and local public health preparedness is every bit as high a priority as the investment in research and development. We have a program of cooperative agreements with all of the States, some major cities, and the territories. One part of that flows through the Centers for Disease Control and Prevention, aimed at State and local health departments. The other part flows through the Health Resources and Services Administration, focused on hospitals and other health care entities.

We have provided a little over a billion dollars in fiscal year 2002, about $1.5 billion last year, and we will award about another $1.5 billion this year. In shaping those cooperative agreements, we have tried to balance broad investments, strengthening public health overall, such as the addition of epidemiologists, the improvement of communication systems, the improvement of laboratories, with things that are highly specific either to bioterrorism or other aspects of public health emergencies, and we will continue that emphasis. We are gratified by the strong response of our State and local partners, and it will continue to be a major emphasis for us.

Mrs. CHRISTENSEN. The administration has requested $150 million less for public health and hospital preparedness grants for fis-

cal year 2005. How can we justify cutting? I also notice, I think I read this week that $480 million was just released for hospitals, and you said at one point $5 billion. Have the States and territories indicated what their level of funding need might be, and how well are we meeting what they have projected their needs are? Because my understanding is that in the hospitals and emergency rooms the staffing is really overstretched, and maybe there are two States out of the whole Nation that can be considered relatively prepared.

Mr. RAUB. I think it is fair to say that, if asked, every one of our State or local colleagues would say that, if more moneys were available, they could use it intelligently. Nonetheless, substantial investments are being made and much of that is at a pace or above what many of them are able to accommodate because of limitations in their procurement systems, hiring freezes, and the like, and we have continued to work with them to try to accelerate some of those investments.

Looking to the future, the fiscal 2005 budget proposes a continued substantial investment. Some of the offset you described is not to take it away from the problem but rather to orient it on another facet; namely, increasing our capabilities for biosurveillance as well as increasing our capabilities for quarantines. So it is a matter of the typical set of choices that go along with the development of any budget, but we believe the aggregate package continues to be strong and will remain among our highest priorities.

Mrs. CHRISTENSEN. Dr. Fauci, you talked about the long time frame to developing vaccines, that it is relatively long, we can't just demand and it is going to be there. In light of that—and we have talked about BioShield—we have had many hearings on that—our Ranking Member mentioned fast cures. Wouldn't it be better for us to focus more of our time and investment on more basic, more generic all-hazard type research to shorten the time frame to develop a countermeasure, rather than, as we are doing in BioShield, preparing to meet agents, some of which we know or we think are likely to be agents, some of which we have no idea on, so when a new agent shows up, we are not going to be able to respond quickly enough to develop a countermeasure? Wouldn't it be better for us to focus on the fast cures approach?

Dr. FAUCI. The fast-cures approach can be either specific for a microbe or it could be more generic. In fact, at the testimony last year, I introduced a concept—and we are following up on that—of trying to develop much more generic antimicrobials against a whole range of microbes, as opposed to going through each individual specific microbe.

The same holds true for vaccination to be able to more generically or globally up-regulate the body's immune system by dealing with the innate immune system so that it could respond across a wide range of microbes.

I do agree with what Mr. Turner said, that we should try, particularly with the combination of both screening and then, as soon as you get a "hit" as we call it, to try to develop very rapidly at least a couple of antimicrobials against all the known threats and use your knowledge of the genomic makeup of the microbes to be able to target.

So there are two general approaches that I believe Mr. Turner was referring to. One is a screening approach, which is more amenable to the rapid approach that he is talking about. And then there is the targeted development, which may not be as rapid but ultimately would also get you good results. I think if you accelerate both of those, the time frame from when you started until the time that you actually have a countermeasure against a microbe will be shortened.

Mrs. CHRISTENSEN. Is that 8 minutes or 5?

Chairman COX. That is 8 minutes. The gentlelady's time is expired.

Mrs. CHRISTENSEN. Okay. I will be back. Thank you.

Chairman COX. The gentleman from Washington, Mr. Dicks, is recognized for 5 minutes.

Mr. DICKS. The gentleman from Connecticut, Mr. Shays, pointed out that if we were truly treating this as a wartime setting, we would be going 24 hours a day. I can remember in my hometown of Bremerton, Washington when they were overhauling and repairing ships during World War II, that they went 24 hours a day, 7 days a week. The President came out there twice to exhort the workers to do more, to do it faster, to restore these ships that had been damaged to the Pacific fleet. And I too share Mr. Shays' concern that this is a very leisurely pace that we are talking. And the cutting of $150 million for these grants again is a demonstration. Can anybody here tell us that public health agencies across the country and hospitals are prepared to deal with a biological attack of some sort? I certainly don't hear that from my doctors and from my clinics out in the State of Washington. We probably do better because we have a few military hospitals there, Madigan and Bremerton Naval Hospital, but I share this same concern that we are doing this at a one-shift-a-day approach. And I just wonder whether we are going to get this job done and get the country truly prepared.

There was one question here I am going to ask all of you. What are the two or three largest obstacles to true terrorism preparedness in the United States? I would like each of you to take a shot at that. Is it money? Is it commitment? What is it? The Congress? What is blocking you from moving out and getting this job done?

Dr. FAUCI. From a research standpoint—and I would like to in my answer very briefly address your justifiable concern, Mr. Dicks, about the slowness of the pace—if we had a product that we needed to make available by manufacturing it, then you put the 24-hour shifts in and make it.

During World War II they were making bullets, they were making tanks. They knew how to make the tanks. When you are dealing with research, there are questions that need to be answered and knowledge that needs to be gained that isn't necessarily as amenable to the 24-hour approach. Once you get a product, then I say put the afterburners on and go after the 24-hour approach.

So my part of the answer to your question to the four of us is that when you are dealing with research, knowledge is one of the major stumbling blocks, and that is why you do research to develop the concepts so that you can get the countermeasures. So from my standpoint that is it. We have been given—.

Mr. DICKS. So the biggest obstacle from your perspective is a lack of knowledge on how to prepare the countermeasures that we need?

Dr. FAUCI. Precisely. From a research standpoint. I am not talking about public health. Others can answer that. But from a research standpoint, it is our race to get the knowledge to be able to develop the countermeasures that we don't have.

Mr. DICKS. Dr. Raub.

Mr. RAUB. Complementing that on the public health preparedness side, I would say the greatest challenge is getting and keeping agreement on the threats and priorities of the threats. I will give you an example of that. When we began our investments 2 years ago in the increased State and local preparedness, one of the benchmarks we set out and asked all of the States to address was to have an epidemiologist for every municipal area within a State that had 500,000 or more people. Virtually every one of the States has achieved that because they and we agree that it is fundamental to public health preparedness.

Other aspects such as the ability to receive an emergency case report around the clock, 24–7, has been aggressively implemented by some States but not others. And I think it is not so much they don't know how, but rather they don't perceive the emergency threat in the same way that other States do, or, frankly, to the degree that some of us do.

So part of our continuing challenge is trying to ensure that communication to get the emphasis on both broad enhancement of public health but also the more sharpened aspect of emergency response. And that is a continuing challenge, especially the further you are outside the Beltway, and sometimes the threat doesn't seem as acute, and we will continue to labor at that.

Mr. DICKS. General?

General MARTINEZ-LOPEZ. Sir, I think I agree with Dr. Fauci. But something else that is a second-level obstacle is sometimes we rely—we have labs all over the country, and the way the scientists go about their business is by reading the articles that are published. It takes us almost a year or 2 years to publish those articles. In order to compress the cycle, what you want to do is to bring those guys together, either to conferences, or, like in the biodefense campus, to a single place where now, having coffee, they can discuss a particular project or a particular problem they have, and that way you can compress the cycle.

And I think one of the things that the biodefense campus is going to allow us to do is exactly that: Bring different agencies, different people approaching the same problem from different angles, and put them together. And we hope that by doing that alone, obviously we are going to foster more structure collaboration, but by doing that we can really compress the cycle and, at the other end, with better products.

Mr. DICKS. Secretary Albright?

Dr. ALBRIGHT. I think I agree with Dr. Fauci's point as well. And I think the basic obstacle fundamentally is time. I think it is not resources. I think this administration has devoted fairly significant resources over the last couple of years to basic research, to threat characterization, to procurement of countermeasures should they be available. I think the real issue is having the time to develop

and the knowledge to develop those countermeasures, making the research work.

Where we have countermeasures, we are, I think, to use your term, we are going 24–7. A good example is the very first procurement that is going to come out under the BioShield is the RPA procurement, and in the meantime we are maximizing—as part of that we are going to maximize production of the AVA vaccine, the existing vaccine, until RPA comes on board. So I think you cannot command discovery, as I think Dr. Fauci said, and I think that is the real issue.

Mr. DICKS. Thank you.

Chairman COX. Mr. Langevin is recognized for 5 minutes.

Mr. LANGEVIN. Thank you, Mr. Chairman.

And, gentlemen, I would like to thank you for participating, being here today. Certainly your insights and expertise have been extremely helpful as we wrestle with some very difficult issues.

In particular, I just want to welcome Dr. Raub here today, with whom I had the pleasure of participating recently in a recent exercise of the National Defense University where Members and agency experts were confronted with a disturbing scenario involving multiple bioweapons attacks across the country. So thank you for being here. The exercise that we were involved with was certainly enlightening and provided a rather chilling reminder of how far we still have to go to ensure that we are adequately prepared to respond to such an attack.

One of the problems that we confronted during the exercise, which involved multiple, nearly simultaneous anthrax attacks on various cities, was determining how to allocate limited stockpiles of drugs when there may not be enough for every person affected. In addition, it became clear that finding adequate personnel to distribute the drugs once they arrived and appropriate locations for distribution would be a major hurdle.

So what I would like to ask is, in terms of stockpile, can members of the panel address adequacy of our current stockpile and what plans, if any, are in place to increase it so that we would have sufficient product on hand in the event of multiple simultaneous attacks or even one attack of great magnitude? And also has consideration been given to working with Canada and other countries to quickly get additional drugs to the right place should the need arise?

Mr. RAUB. Thank you, sir. I will start off, and others may want to add here. The current Strategic National Stockpile—and I will focus specifically on antibiotics not only because that is the major part of it but that was the focus of the exercise in which you and I and others engaged—that stockpile is enough for 13 million individuals for a 60-day course of treatment. Plans are underway beginning this year and going through fiscal year 2006 increase that stockpile to the order of 60 million treatment courses for 60 days, recognizing that we need a broader capacity.

Mr. LANGEVIN. That will take place over how much time?

Mr. RAUB. Between through now and fiscal 06 as our proposals are considered.

The second part of that, as you indicated, is one of our weakest links right now is getting the material from the airport or wherever

we deliver it into people's mouths. All of our public health components around the country know how to set up and operate a point of dispensing, and many do it routinely for childhood vaccination or for outbreaks such as meningitis, but none of these communities has ever been challenged to do it on a very broad scale in a very short period of time. And it is our new understanding of the anthrax threat in particular, where an area of square miles could be covered, and we would not know who was exposed, but we would have to start antibiotic treatment while we figure that out, that becomes a major challenge.

That is the thrust of this recent plan announced by the Department for a Cities Ready Initiative to focus on 21 major cities in collaboration with our colleagues in Homeland Security, the United States Postal Service, and others, to make more robust the metropolitan capability to deliver and dispense antibiotics locally, to supplement that with Federal resources as needed, including those of the U.S. Postal Service, and in general to get the more rapid penetration that would give us time to understand better the nature of the exposure and to go on with the longer-term public health measures.

The final part of this is to encourage more local deployment of antibiotics for the immediate needs of the community, especially for medical personnel, for fire, police, transportation operators, and others—that there would be enough material on hand immediately to ensure some stable function of that infrastructure while the larger response was being readied.

Mr. LANGEVIN. Anyone else?

Dr. ALBRIGHT. Well, another issue that generated a great deal of discussion at the exercise was the question of information sharing with the public at large as well as State and local officials and specific industries or sectors that might be particularly affected. We all agreed at the outset that in any crisis like a bioterror attack that it was critical that those who needed information would receive it in a calm, detailed, and coordinated manner basically, obviously, to engender trust, minimize panic, and ensure cooperation and assistance of those in a position to help. What we couldn't get a clear sense of is whose responsibility such communications are going to be or are.

My sense is that both a public information and education campaign as well as information sharing among jurisdictions and industry sectors should be coordinated through the DHS so that there is one clear voice speaking to Americans and one defined clearinghouse of information flowing to and from various stakeholders.

So I would like to ask the panelists to describe their understanding of the procedures and protocols currently in place for communicating with State and local governments, the private sector, and the public in the event of a bioterror attack; and do you feel these mechanisms are adequately defined and understood among all relevant agencies; and is there a plan in place for what information to share at what time; and are the basic elements of a public information campaign already in place so that it could be quickly implemented in an emergency?

Dr. ALBRIGHT. There are several aspects to that. There is sharing with the local public health officials, which I will defer the answer to that to Dr. Raub.

In terms of communication strategy, the department has been fairly proactive in developing a suite of communications strategies, I guess is the right word, for a wide variety of events—radiological, nuclear, biological—but I would say that is work that is just now—it is not mature yet. Exactly how to communicate to the public what the risk is, how to keep the issues surrounding—what precisely the response of the public should be if a particular event were to occur, for example, a radiological or biological attack, is something we are working, for example, with the National Academies on. It is an area that we are focused, but it is a work in progress.

Mr. LANGEVIN. Where along that process are you right now?

Dr. ALBRIGHT. Excuse me?

Mr. LANGEVIN. In terms of a timeline, where are you in that process to having—.

Dr. ALBRIGHT. We are proactively—as I said, we have a contract in place with the National Academies of Sciences to—and I believe that has been underway for several months—to develop communication strategies in these various areas. I believe it is a 1-year contract, but I am not certain of that. This is actually being operated under our public affairs shop, and I will certainly be happy to get back to you after the hearing with more information on that if you wish.

Mr. LANGEVIN. Yes, I would like that. Thank you.

Dr. Raub.

Mr. RAUB. If I could just add quickly that your question has several facets, and I won't try to touch all of them, but at the national level under Homeland Security Presidential Directive No.5, any event involving two or more of the Federal agencies looks to Secretary Ridge to be the coordinator of those activities, including the coordinator of the communication aspects of it.

At the local level, those cooperative agreements that I mentioned in responding to Mrs. Christensen before include a component on public communication, and we have asked each of the State and local health departments to prepare themselves not only on their own, but in conjunction with the emergency management officials and their political leadership and others, to have the capabilities to, as you say, apprise the public actively in a firm but low-key way to not only let them know what is happening but also to enlist their cooperation; because if we are at a major response such as something requiring rapid distribution of antibiotics or vaccination of a large group of people, no matter how good our medical or public health capabilities are, if we don't have cooperation from the public, and instead we have civil disorder or chaos, it just makes that medical delivery almost impossible. Those are just two aspects of it but this continues to be a major concern and emphasis for us.

Ms. DUNN. [Presiding] The gentleman's time has expired. I thank the gentleman. Next we will call on the gentlewoman from Texas, Ms. Jackson-Lee.

Ms. JACKSON-LEE. Thank you, Madam Chairperson. I thank the witnesses for their presentation as well.

Let me try to characterize the attitude that I have or the sense of concern that I have, using one or two anecdotal stories or at least reflections on the week's recent events, first being the pronouncement by the Attorney General just last week, during the week of memorializing and honoring our fallen soldiers, of a terror alert or at least a terror pronouncement. I am not sure what it was intending to do. But for those of us in our communities, our local districts, it was confusing at best because, obviously, it was a stand-alone activity by the Department of Justice and the FBI Director, and only later did Secretary Ridge either suggest that he gave his approval—but I can assure you that those on the homefront, which is what I believe the Homeland Security Department and this committee is to be about, we are certainly concerned about the inside-the-Beltway, but our work is really outside the Beltway, and really that announcement fell on deafened ears, jaded minds, and people basically ignored it. That was the context in which it was received.

Just as an aside that is not really pertaining to your business, yesterday we were debating a constitutional amendment dealing with the potential of losing 218 Members of Congress, maybe all at one time. And the reason why I raise that with you is that even that monumental debate did not warrant this body giving it more than 30 minutes a side to talk about what would happen if we did not have this Congress in place or government in place.

I only use these examples to say that I am equally concerned that many think of terror as airplanes flying into buildings and have not yet understood the potential biological, chemical, or radiological weapons, except for the fact of the terminology "dirty bombs." At least the public understands that, but I don't know if they perceive that it will come in Cleveland, Ohio, or Houston, Texas, or some rural hamlet or village or suburban location.

And that is my frustration where we are today. I think this is an important hearing, but I would like to raise these points, but I would ask any of you to join in, but specifically I would like Dr. Albright and Dr. Raub to answer these questions, and they build upon my colleagues' concern, and that is about our public health and hospital infrastructure. But I also want to speak specifically to local clinics, health clinics.

Many of us are advocates of local community health clinics, and my concern is when you use the term "local," are we reaching as far into the infrastructure as those local clinics?

My first question is, enunciate for me or give me an understanding—and I am going to give you all the questions at once—what are the accountability standards that have been put in place? Where are they? Are they posted up on a wall? Does each medical director have them or public director have them? Do the city and county directors have them? And what is the guidance being given? Is there a 1–800 number or emergency number that someone can call to immediately grab hold onto the instructions? We can talk about large intent, but if they are not transferrable, they are not working.

On the outsourcing do we have a firewall—when we talk about outsourcing, production of biodefense agents, do we have a firewall to protect the Nation against sabotage of production of those bio-

defense agents, or are we randomly outsourcing with no indication at all?

The last question deals with what I started out with, my local community health clinics. Are they in any way connected? And I am sure you will say connected to their major body, whether it is State or local; but are they connected? Is there some way of having tentacles to that embedded community clinic that is somewhere in someone's community, whether it be rural or urban? And I would appreciate it if you can attack this question with a vengeance.

Let me just for a moment—and I know I am on this last point here—you have a problem called BioWatch, Detect to Treat, and there was an incident in Houston, tularemia, where it did not work. I think you are aware of it, and I don't want to go on long with the question, but if you can comment on that, and if not, I will welcome that in writing. But Dr. Raub and Dr. Albright, and others who may want to join in. Thank you.

Mr. RAUB. With respect to your first question about accountability standards and guidance, the cooperative agreements that I mentioned before from both of the agencies include items that we call critical benchmarks. These are milestones on the road to preparedness, but things that are to receive the highest priority and things that we believe can be and should be achieved in a short period of time.

Ms. JACKSON-LEE. Are you speaking about standards? That is what I asked about, accountability standards. You are talking about benchmarks.

Mr. RAUB. Well, some of them are quantitative now. Others are our first estimate, because we are not sure exactly what the final standard should be. I gave the example before of 1 epidemiologist for every metropolitan area of 500,000 people or more. We think that is a good starting number. We don't know that that is the precise standard that ought to hold for all time, but it was a near-term target that we believed every State could and should achieve, and we will continue to make that kind of emphasis.

As these cooperative agreements go on, we will sharpen and build on those critical benchmarks, trying to make them more precise and more quantitative and closing in on standards, as you would describe it, because I share your view that we need to be communicating as clearly as we can about what we are all trying to achieve.

With respect to the emergency response, every one of the State health departments is well connected to the Centers for Disease Control and Prevention and knows how in the face of an emergency or even any uncertainty to make the contacts at CDC to get the kind of technical assistance they need. CDC in turn is well connected not only with our Office of the Secretary but with colleagues in the FBI. We are well connected with the Operation Center at the Department of Homeland Security, and we like to think we are getting better and better at providing that kind of emergency assistance and response.

Ms. JACKSON-LEE. Dr. Albright.

Dr. ALBRIGHT. What I can comment on is on your question about the BioWatch incident in Houston. Actually I think that is an example of the system first working quite well and a good example

of interagency cooperation and cooperation between Federal and local public health entities.

First let me state what actually happened. The BioWatch system that was in Houston in fact did detect tularemia and in fact it was tularemia. The system did work. The pathogen was later sequenced at CDC and was confirmed to be that. They were very weak hits. When the incident occurred, what we immediately did was to begin coordinating with CDC in two specific areas. The first was in the arena of a public announcement. So in terms of public affairs, we worked jointly with CDC to craft some—frankly, some talking points for the local public health officials should they decide that they needed it.

The second thing we did, very importantly, was again working with CDC and the local public health people, was we increased disease surveillance in the area. So we had these very weak hits of tularemia in the system. We then—CDC actually and the local public health authorities notified the local clinics to—essentially if they got a certain set of symptoms, to rule out tularemia was basically the instructions they got, and thereby substantially increased our ability to detect the disease, which, if detected, is eminently treatable.

So what it was, was a very good example of our ability to work very closely with CDC and HHS on an event such as this. Then secondly, our ability jointly at the Federal level to work with the public health authorities locally. They were basically told that they were in charge of the incident, and they were put in charge of the incident. And I have to tell you, I don't think they believed it until we actually did it, that they were allowed to run it. They were allowed to run the public affairs aspects of it. They were allowed to they interacted with their local medical community directly.

Ms. JACKSON-LEE. They waited several days to determine that that was what the substance was or what the item was.

Dr. ALBRIGHT. Excuse me. What actually happened was, the way we get the hits in tularemia is through a very robust analysis. This was not a false alarm. No one thought it was a false alarm at the time. And all I can say is that the subsequent analysis just confirmed something that we really knew to be true on the ground, I believe the local public health people knew to be true on the ground as well.

Mr. RAUB. Let me just add as somebody who spent many hours in the Operation Center those several days, as Dr. Albright indicated, we had a true positive. It turned out to be environmental noise, not a terrorist attack, and frankly we thought it was environmental noise. The officials in the city of Houston, in Harris County in the State of Texas, could not have performed better in our judgment in terms of the very deliberate way they proceeded in the face of the uncertainty but the likelihood that we had something that was an environmental cause rather than a terrorist attack. Nonetheless, the surveillance efforts they put in place as a precaution were a model, I think, of what other cities might do. And from my perspective I viewed that as some of that State and local money at work manifesting itself in a demonstration that they are indeed moving to heightened preparedness.

Ms. DUNN. The gentlelady's time has expired.

The ranking member of the committee, Mr. Turner of Texas, has an additional question.

Mr. TURNER. I won't take a question because I think we need to move to the next panel. But I want to make a request and maybe, Dr. Fauci, if you could do this for us it would help us as a committee. You have heard people on both sides of the aisle talk about their sense that we are not doing this 24–7, that we are not making the kind of commitment that we need to make, and so it would be helpful to us if you could prepare for us and perhaps give us a briefing outside of the hearings, just a briefing with members that are interested and staff, on the total dollars that we are currently spending and the kind of grants and other activities that are ongoing through your agency and any others that you have to bring in, which I am sure you are aware of, to a accomplish the goals of that rapid-cures act that we have introduced, so we can get a sense of how great a commitment are we making to this basic research that is necessary to shorten this time frame and the right options on how to do it.

The other presentation I would request from you to present perhaps in the same fashion to the staff and the members who are interested in a briefing setting is the amount of money that we are committing to finding the countermeasures to the various pathogens that we know we are worried about and maybe do the class A, the class B, the class C. Let us just see the dollars that we are spending, the grants, the total efforts that we are making in those areas to give us a sense of that.

And then the final one is a request that you are familiar with, I think, that came from staff as they were trying to look into the financial management review procedures that you use before you enter into a contract with a private sector company to do some work for you; because, as you know, there is some information out there now that this biotech company, VaxGen, that has over $100 million in government contracts, that there may be some evidence of accounting irregularities there, and I think they have been threatened with having their name delisted from NASDAQ, and it has given us concern.

If you could provide us a briefing about that issue so that we can have some assurance that when you are granting these multi-million-dollar contracts, that we are giving them to companies that are not going to go bust on us.

Dr. FAUCI. I would be happy to do all three of those requests, Mr. Turner, and I will have my staff work with your staff to set up the briefing times as soon as we possibly can.

Mr. TURNER. Thank you. Thank you, Madam Chairman.

Ms. DUNN. Thank you. And thank you very much, gentlemen, for appearing before us today. It has been very useful and we appreciate your coming here.

The Chair would like to ask the second panel to be seated, please.

We welcome our new panel. Thank you for being with us today. Let me remind you that if you could keep your opening statement to 5 minutes, your written statement will certainly appear in the record, and as a result we would be able to allow our members to have time for questioning. Thank you very much.

Ms. DUNN. Why don't we start with Dr. Johnson Winegar, and then we also welcome and we will hear next from Dr. Shelley Hearne.

STATEMENT OF ANNA JOHNSON-WINEGAR, PRIVATE CONSULTANT

Ms. JOHNSON-WINEGAR. Thank you, Madam Chairman, and other members of the committee, for the opportunity to appear before you today to address this extremely critical topic that I have thought about for essentially most of my professional career.

Just to set the stage, I wanted to inform you that I have previously served as the Deputy Assistant to the Secretary of Defense for Chemical and Biological Programs, and recently retired from that position. I do have a Ph.D. in microbiology and I am currently a private consultant in those general areas.

When I think about the area of biodefense and bioterrorism, I feel very strongly that a comprehensive approach is required to address the full spectrum of things that can go on. First and foremost, I feel it important that we must significantly increase our resources in the areas of intelligence and threat assessment. In my opinion, unfortunately, our expertise in this area is indeed quite limited.

Another important area that I think is quite overlooked is that of biodetectors. The current biodetectors that we have are characterized by the scientific community as detect-to-treat rather than detect-to-warn, and this is due to the lag time between collection of samples and identification of the pathogen. And while this is a good first-step approach, without more definitive intelligence, the cost to establish and maintain a sufficient number of these biodetectors throughout the United States is prohibitive.

And I think that perhaps even more importantly than working on improvements in biodetector technology, for I do believe the improvements will come incrementally, is the need for a concept of operations. In other words, what happens when the alarm goes off? Who makes the decisions? Where are the supplies that we needed? And finally, after a potential attack, there is the whole problem of residual contamination and clean-up.

I think that much more emphasis needs to be placed on new decontaminants that are environmentally friendly, safe to use on humans, and sensitive electronic equipment, ones that can be disbursed over large areas, ones that work quickly and are inexpensive.

And, finally, any robust science and technology program that addresses bioterrorism and biodefense needs all of these aspects, plus medical countermeasures.

Realizing the lack of a commercial market and poor incentives for the industry has been one of the problems in getting the pharmaceutical firms to develop the drugs and vaccines that we need. I think a lot of information has been provided by the earlier panels on the work that is going on in what I characterize as basic research, and there is the BioShield legislation to address the procurement of these items. However, I feel that there is a major gap in the advanced development areas. We need additional work done on validated animal models. We need a lot more work done in both

preclinical and clinical trials so that before these products come to market, we are sure that they are both safe and effective.

I would call your attention to the recent report by the Institute of Medicine on giving full measure to medical countermeasures in which they describe a number of problems associated with the current approach and they make specific recommendations for alternatives. I firmly believe that a vigorous effort must be made to shorten the time frame to develop new medical countermeasures.

Clearly the Department of Defense has invested for many years in the area of medical countermeasures. Now the budget of the Department of Health and Human Service has increased dramatically, now providing over $1–1/2 billion. This indeed dwarfs the investment made by the Department of Defense, and it has initiated an obvious shift from DOD to HHS as the primary funder in biological research against terrorists' use of biological agents.

However, the history of NIH has been one of investigator-initiated research rather than one that is based on threats or driven by requirements. While the NIH has traditionally been strong in basic research, they have much less attention on product development and licensing of new products.

I think that we all agree that bioterrorism is a major threat to us, and I think the priorities need to be established across the various Federal agencies, all the way from analysis of the threat and a true prioritization of the vast array of projects that could be funded. Not every project of purely scientific interest deserves funding. Measures of effectiveness must be established and publicized. Areas of common interest to the individual departments must be leveraged to shorten the timelines. Formal communication and collaboration must be established that transcends the particular individuals involved in the programs. Budgets must be aligned. Senior officials must be held accountable, and results are imperative.

I would be happy to answer any questions that the committee members may have.

Mr. TURNER. [Presiding] Thank you, Dr. Winegar.

[The statement of Dr. Winegar follows:]

PREPARED STATEMENT OF DR. ANNA JOHNSON-WINEGAR

INTRODUCTION

Mr. Chairman and distinguished committee members, I am Dr. Anna Johnson-Winegar. Thank you for the opportunity to appear before you today to address this extremely critical topic. I am the former Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense Programs, having served in that position from October 1999 until my retirement in June 2003 after 37 years with the Department of Defense. I have a PhD in microbiology and I am currently engaged in private consulting in the general areas of chemical and biological defense, biotechnology, medical product research and development, and other related areas for both government and commercial clients.

I am here today to discuss my thoughts on how the United States is proceeding toward developing a comprehensive biodefense strategy. I think we are all aware that the tragic events of September 11th and the anthrax cases in the fall of 2001, as well as more recent incidents with ricin have greatly heightened the public's awareness of the threat of biological terrorism. The creation of the department of Homeland Security last year was a major step in raising the level of importance of all aspects of security for the people of the United States. The focus of today's hearing, and the basis for my remarks deals specifically with the threat of bioterrorism-one aspect of the broader threat of weapons of mass destruction (WMD).

A COMPREHENSIVE APPROACH IS REQUIRED

When addressing the full spectrum of a potential attack with a biological agent, it is helpful to identify responses across a continuum. Clearly, long before any such incident, we must significantly increase our resources in the areas of intelligence and threat assessment. Unfortunately, our expertise in this area is quite limited. While there have been modest efforts to capture information from employees who worked in the U.S. offensive biological warfare program that was cancelled by President Nixon in 1969, much of their understanding of how to make a biological organism a weapon has been lost. Among the goals of the National Biodefense Analysis and Countermeasures Center (NBACC) is support for intelligence activities and characterization of biological threats. This will take years of hard work to establish core capabilities and build a strong cadre of personnel. This group will also be challenged by the need to think creatively. The use of the postal system to deliver anthrax spores is but one example of how little our current defensive program understands the broad range of possibilities for biological terrorism.

In the time immediately preceding a biological attack, the best approach is a detection and warning system. Current bio-detectors are characterized by the scientific community as "detect to treat" rather than "detect to warn". This is due to the lag time between collection of appropriate samples and identification of potential pathogens. The BioWatch program, currently set up in approximately 30 cities in the U.S. makes use of environmental monitoring in specific locations. While this is a first-step approach, without more definitive intelligence, the cost to establish and maintain a sufficient number of biodetectors throughout the United States is prohibitive. Current detector systems use triggers that respond to increased particles in the air, followed by laboratory analysis of samples that are collected by one of several means. Current identification systems rely on specific antibodies or nucleic acid probes to identify' the specific agent. Obviously then, these systems are limited in their capability since, by design, one must know what you are looking for in advance. More research is desperately needed on generic systems that can act as a first alert. Some approaches toward these types of systems include receptor based technology and living cells that may respond to any number of toxins, chemicals, or biological agents. The level of sensitivity and specificity for biodetectors still needs improvement. While some assays are very sensitive, others are not yet at the level of being able to detect small doses which can cause human illness.

However, perhaps even more important than improvements in detector technology (for they will come incrementally), is the need for a concept of operations. Assuming one had a "perfect" biodetection system-i.e., one that had the ultimate degree of sensitivity, an absolute ability to distinguish false positives and false negatives, and one that could operate without fail for long periods of time, the question still remains: Who is responsible for analyzing the information, what is the chain of command for disseminating the information, and what response can be taken? True, for some of the biological threats, prompt initiation of antibiotics may be effective in preventing onset of disease. For others, post exposure vaccination may be appropriate; however, sufficient pre-clinical and clinical data are needed before this approach can be advocated on a large scale. Finally, there are still many agents on the threat list for which there is no treatment, and therefore, a "detect to treat" approach is doomed to failure.

Another approach at protection following an alarm, is that of individual and collective protection. This is the approach used by the DOD to protect military members in chemical-biological environments. While it may be impractical to provide the entire population of this country with protective masks, this is indeed the approach taken by Israel. It seems apparent that more work is needed in the areas of improved physical protection for the citizens of this country.

Finally, following a potential terrorist attack with a biological agent, there is the problem of residual contamination and clean-up. This has turned out to be a major problem in sufficiently cleaning facilities that were contaminated with anthrax spores. New decontaminants are needed that are environmentally friendly, safe to use on humans and sensitive electronic equipment, can be dispersed over large areas (both open and enclosed, work quickly, and are inexpensive. It would be desirable to have one decontaminant that is effective for both chemical agents as well as biological agents (specifically anthrax spores).

A robust science and technology program is needed that covers all aspects mentioned above-i.e. intelligence, detection, individual and collective protection, and decontamination. Medical countermeasures are the final component of a comprehensive approach and will be discussed in the following section of my statement.

MEDICAL COUNTERMEASURES FOR BIOLOGICAL AGENTS

A significant effort is being undertaken to improve the status of medical countermeasures for biological agents. This issue first received a high priority within the Department of Defense during Operation Desert Shield/Desert Storm. The leadership of the Department, as well as the nation as a whole, came to realize that we went into that conflict with only one vaccine licensed by the Food and Drug Administration. The anthrax vaccine had been approved in 1970, and had been is limited use by at-risk laboratory workers, some veterinarians, and a few commercial industries (wool mills).

Surge capacity for large quantities of this vaccine was an immediate need, however, the pharmaceutical industry was not able to respond. Further, there were no products available that had been specifically licensed for treatment of anthrax (which means indicating that on the product label and package insert). Animal studies conducted by the DOD were instrumental in providing data to show that administration of antibiotics post exposure were effective (under the controlled conditions of the experiments). Subsequently, several antibiotics have now been approved by the FDA for treatment of anthrax. However, post-exposure use of anthrax vaccine is not yet approved by the FDA and such treatment must be conducted under the rules of Investigational New Drugs. Beyond anthrax, there were almost no products available for immunization or treatment except very limited quantities of a toxoid for *Cl.botulinum,* and even more limited supplies of antitoxin for treatment. Realizing the lack of a commercial market and poor incentives for the industry, the DOD undertook a number of different studies to address the problem. Meetings with industry raised their specific concerns, namely: indemnification and liability; long-term commitment of government funds; setting priorities for vaccine production (i.e. balancing current marketable products versus developing a stockpile of vaccine for limited use); needs for additional studies to validate animal models and conduct necessary pre-clinical trials; expenses associated with larger clinical trials, even if only to establish safety and immunogenicity of a new product; and bio-safety and bio-security concerns. The concept of a Government Owned–Contractor Operated (GOCO) vaccine facility was supported within the DOD budget request in the mid–1990's, but was subsequently withdrawn in favor of an approach that relies upon private industry to meet the vaccine needs of the DOD. This Joint Vaccine Acquisition Program (JVAP) has been in place for over five years, and no new products have been licensed. The recent report by the prestigious Institute of Medicine entitled "Giving Full Measure to Medical Countermeasues" describes problems associated with the current approach and recommends alternatives for both the research and development aspects of a biodefense program as well as procurement issues. A vigorous effort must be made to shorten the time frame for new medical countermeasures.

In the time since the Gulf War (now more than 10 years), we still have no new medical countermeasures licensed and available. (I am discounting the additional quantities of smallpox vaccine since that was not a result of new research and development). Now, the budget of the Department of Health and Human Services has been increased dramatically, providing over $1.6 B in fiscal year 2004. This dwarfs the investment made by the DOD, and it has initiated an obvious shift from DOD to HHS (NIH and NIAID) as the primary funders for biomedical research against terrorist use of biological agents. However, the history of NIH has been one of investigator initiated research rather than one that is threat based or driven by requirements. Further, the NIH has traditionally been strongest in basic research, with much less attention on product development; clinical trials, and licensing of new products. New regulations on handling select agents may deter some academic institutions (the traditional strength of NIH grants) from working in this area. It will take years for some of the basic research that is just getting started to pay off. It will be important to maintain the momentum that has been started.

THE ROAD AHEAD

Realizing that the threat of bioterrorism or use of biological agents by a traditional adversary could cause irreparable damage is a most dramatic incentive to the various Departments of the government to coordinate and find accelerated ways to address the problem in the shortest amount of time possible. The Department of Homeland Security has the lead in most areas of the science and technology programs, with the Department of Health and Human Services having the lead in medical countermeasures. The role for the Department of Defense is still unclear in many aspects, but it is obvious that much of the knowledge we have today is resident within the DOD. It is essential that we do not waste time reinventing the wheel, or repeating work simply because of parochial interests.

First priority should be given to a thorough analysis of the threat and a prioritization within the vast array of projects that could be funded. Not every

project of purely scientific interest deserves funding. Measures of effectiveness must be established and publicized. Areas of common interest to the individual Departments must be leveraged to shorten time lines. Formal communication and collaborations must be established that transcend individuals involved in the programs. Budgets must be aligned to avoid duplication. Senior officials must be held accountable. Results are imperative. The future welfare of our country depends on it.

Mr. TURNER. Dr. Hearne.

STATEMENT OF DR. SHELLEY A. HEARNE, EXECUTIVE DIRECTOR, TRUST FOR THE AMERICA'S HEALTH

Dr. HEARNE. I hope to be just as efficient in covering all these bases.

Good afternoon and thank you for holding this hearing on a very important issue. I am Shelley Hearne, the executive director of Trust for America's Health, a nonprofit, nonpartisan organization dedicated to preventing epidemics and protecting people.

Everyone in this room knows full well about the threats and concerns of bioterrorism. Certainly the Hill has experienced many of those attacks in person with ricin and anthrax. What is important to remember is that the 2001 attacks were a relatively minor event that absolutely overwhelmed our public health system. They overwhelmed our labs. They besieged our few epidemiologists out there and they revealed that most States don't have a bioterrorism plan. In my home State of New Jersey, postal workers and others were told to go find their personal doctor and to get the antibiotic Cipro if you had a doctor, because the local health agencies were not prepared to do delivery and emergency distribution of those supplies. This was not the American public health system's finest hour.

The good news we had in that event is that it was a strain that was not drug resistant and it was also responding to a widely available antibiotic.

But having stockpiles of medicines and vaccines will not protect us without a fully functional public health system that includes those disease-tracking systems that can quickly pick up an event and have the labs that can do the biological and chemical testing to figure out what that agent may be and—critically—the public health workforce who knows how to rapidly respond.

It is the teamwork between the pharmaceuticals and the public health system that is going to prevent a pandemic epidemic. Its only bottom line is—I will show my older days as an aging jock here—but your team is only good as your weakest player, and the problem is that the public health system has been sitting on the bench for decades now with neglect.

After those 2001 attacks, the administration and Congress recognized those public health gaps and quickly responded by investing nearly $2 billion to jump-start the Nation's bioterrorism preparedness efforts. The question now is, are we better prepared? And the answer is, not yet.

Our recent report that the Trust put out found that States are only modestly better prepared to respond to a health emergency. We have seen some very good progress in the area of communications in developing those initial plans and making sure even that the bioterrorist leaders were getting connected to homeland security frontline responders. But our report also showed there is enormous room for improvement. We examined 10 key indicators in

every State, looking at how well prepared they are. We found that almost 75 percent had scores of 5 or lower.

Let me run through some of the particularly serious shortcomings we found. We found that only two States had achieved full readiness, or the green status, to receive, distribute, or administer emergency vaccinations and antidotes from the Strategic National Stockpile. Since then, another State has joined the ranks, but we have also heard reports that as many as six States have actually regressed in their current status. We found that only six States had sufficient laboratory capacities to deal with a major public health emergency.

Ms. HEARNE. We also found an enormous public health workforce crisis, particularly with epidemiologists, environmental specialists needed for chemical events and other trained experts

Other initiatives such as the U.S. Postal Service are intriguing ones that we need to consider, but they do not address the dire absence of needed public health professionals. Bottom line is the decisions about pediatric doses, for instance, need to be made by a doctor and not a delivery man at the door.

Nearly 66 percent of these States, which are facing budget crisis, have also cut funding for their public health activities. This finding seriously dilutes the impact of the Federal investments that have been made for bioterrorism.

To be battle-ready with our public health defenses at all levels—Federal, State, and the local levels—it is going to take years of a sustained commitment, funding, and oversight.

The Trust for America's Health is recommending the following actions:

One is that HHS has informed Congress about plans to redirect $55 million of State and local bioterrorism preparedness funds to new initiatives, including the 21 high-risk cities, and plans to activate the U.S. Postal Service for stockpile delivery. Under that proposal, every State will receive a cut of over $1 million. Shifting money from one preparedness initiative to another is not the solution today for nationwide bioterrorism readiness, especially when we are finding that all States have still significant areas of vulnerability. The House Labor-HHS Appropriations Subcommittee should be urged to continue the funding to State and local preparedness initiatives and find additional dollars to fund that city readiness initiative.

In addition, it has been noted earlier that the proposed 2005 budget does have an 11 percent cut to the State and local preparedness activities. The bottom line is that our biological defenses are far too important to shortchange at this point, and in fact what we recommend is that an independent review is conducted to look at current expenditure needs and also to ensure that systems of accountability are being put in place.

Lastly, I would like to point out that very important initiatives have been raised recently, such as BioSense, BioShield, BioWatch, but one of the concerns that is being raised today is that there really is no bio game plan. The Trust is worried that many overlapping jurisdictions, lack of coordination amongst the various Federal agencies; that there is no plan between the multitude of these interagency initiatives; that we need to have a clear leader in

charge; that a bio game plan is a critical element so that we understand the different parts and ensure that teamwork.

Certainly terrorism thrives on uncertainty, and we don't know what the next attack may be, if it is smallpox, sarin gas or a small radiologic explosion. We must continue to invest in these important programs like BioShield, but you cannot accept that vaccinating the public is the solution unless you have that equal rapid response, highly trained, well-equipped Public Health Service to rapidly detect, manage, and contain all health emergencies. It is the team work that we need in the United States, and I hope that through this committee's work we can continue to urge that progress and direction. Thank you.

Mr. SHAYS. [Presiding] Thank you, Doctor.

[The statement of Ms. Hearne follows:]

PREPARED STATEMENT OF DR. SHELLEY HEARNE

Good afternoon. I am Dr. Shelley Hearne, Executive Director of Trust for America's Health (TFAH), a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. I would like to thank Chairman Cox, Ranking Member Turner and the entire Select Committee on Homeland Security for holding this important and timely hearing. On behalf of Trust for America's Health, I appreciate the opportunity to testify about the role public health plays with respect to homeland security, particularly in the event of a biological, chemical or radiological terrorism event.

Since September 11, our nation has faced a series of dramatic wakeup calls with respect to the state of public health preparedness and we have repeatedly seen that the country is ill-prepared to respond to a large-scale health emergency. The 2001 anthrax crisis was a relatively minor event, yet it overwhelmed the nation's limited public health laboratory capacity, besieged epidemiology investigators, and revealed that no emergency pharmaceutical distribution system existed. In my home state of New Jersey, postal workers and others who were potentially exposed to anthrax were told to go visit their personal doctor to obtain the antibiotic Cipro, since the local heath agencies did not have the ability to distribute emergency supplies. This was not the American public health system's finest hour.

The good news was that this strain of anthrax was not drug resistant and was treatable with a widely available antibiotic. However, having stockpiles of effective medicines or vaccines will not protect us without a functional public health system that includes disease tracking systems to quickly detect an attack, labs that can identify the biological or chemical agent, and a trained public health workforce that can rapidly respond.

As Americans we have long taken special pride that our nation has set the pace for disease prevention and control worldwide. But today, the nation's public health system is being stretched to the breaking point.

Congressional approval of $5.6 billion for Project Bioshield represents one step forward toward better bioterrorism preparedness in America.

Smallpox is a good example of how important it is to have both effective countermeasures and a competent public health system. The Department of Health and Human Services (DHHS) invested wisely in expanding and enhancing the nation's smallpox vaccine supply. In the event of an outbreak, the strategy is to "ring inoculate." Executing this strategy requires astute clinicians to notify public health officials or disease surveillance systems capable of detecting a possible smallpox event, labs that are able to rapidly test and confirm smallpox cases, and deployment of rapid response teams who can deduce who has been exposed and inoculate anyone possibly exposed. If managed correctly, a smallpox event could be caught early and contained. The team work of pharmaceuticals and public health could prevent a global pandemic. But a team is only as good as its weakest player.

The Nation's Current State of Public Health Preparedness

Unfortunately, due to decades of neglect, America's public health system has been sitting on the bench. Following the terrorist attacks of 2001, the Administration and Congress recognized that significant gaps in public health made the nation vulnerable to attack and responded quickly and appropriately by investing nearly $2 billion to help jump start our nation's bioterrorism preparedness efforts. The infusion

of funds into the public health system was sorely needed and most welcome. Yet, two years of bioterror funding cannot make up for decades of underinvestment in the nation's public health system.While progress has been made in state and local preparedness for public health emergencies, much more remains to be done.

Six months ago, TFAH released a state-by-state report, assessing whether or not the nation was better prepared for another terrorist attack or other major health emergency given the $2 billion federal bioterror investment over the last two years.

The short answer is: "not yet."

Our report, *Ready or Not? Protecting the Public's Health in the Age of Bioterrorism,* found that states are only moderately better prepared to respond to health emergencies than they were prior to September 11. We found that some good progress has been made in most states to improve communications with the public and between health agencies. Every state had at least an initial plan on paper of how to mobilize public health resources in the event of a terrorist attack.

However, the report also found that there is much room for improvement. The report examines 10 key indicators to assess areas of improvement and areas of ongoing vulnerability in our nation's effort to prepare against bioterrorism and other large-scale health crises. We found that nearly 75 percent of states earned positive marks for only half (five) or fewer of the 10 possible indicators.

Some of the most serious shortcomings include:

- In December 2003, only two states had achieved full readiness or "green" status with respect to receiving, distributing, and administering emergency vaccinations and antidotes from the Strategic National Stockpile. Since then, another state has joined their ranks. At the same time however, six states have reportedly regressed with respect to their stockpile status. Moreover, there is confusion and uncertainty about the roles and responsibilities of federal agencies, including the Departments of Homeland Security (DHS) and Veterans Affairs (DVA) and the Centers for Disease Control and Prevention (CDC).
- Only six states report that they have sufficient laboratory facilities should a major public health emergency occur, such as a mass mailing of anthrax, simultaneous release of sarin gas in U.S. subways, or even a potential outbreak of plague. These findings build on those of an earlier TFAH report, *Public Health Laboratories: Unprepared and Overwhelmed.* This study found that even fewer state public health laboratories had the ability to detect chemical weapons in its citizenry. The Association of Public Health Laboratories (APHL), found that only eight state public health laboratories have a chemical terrorism emergency response plan in place. This observation is even more alarming in light of the ricin incident on Capitol Hill earlier this year.
- There is a serious public health workforce crisis, including a shortage of epidemiologists and other trained experts. Rather than recruiting and training a new public health workforce, which requires a serious investment of time and money, many states had planned on mobilizing National Guard personnel in the event of a health emergency to deliver medicine and equipment from the Strategic National Stockpile. Yet, as we have recently seen, these troops may be deployed elsewhere, leaving millions of Americans vulnerable during a public health emergency. Alternative initiatives, such as using the U.S. Postal Service, are intriguing, but fail to address the dire need for more public health professionals. Decisions about pediatric doses, for instance, need to be made by a doctor, not the delivery man at the door.
- Nearly 66 percent of states, facing budget crises, have cut funding for public health activities. This seriously dilutes the impact of the federal government's investment in bioterror preparedness.

Since TFAH released its report in December, similar national investigations have confirmed our findings. In February 2004, the General Accounting Office (GAO) issued a report detailing the preparedness gaps nationally, including the discovery that no state had completed all CDC program requirements. Just days ago, the RAND Institute found that in California—a state that TFAH had ranked as one of the best prepared in the nation—there was enormous variability in city and local public health readiness.

What Can the U.S. Do Now to Better Prepare for a Bioterror or Chemical Terrorism Event?

The American public health community has a solid understanding of the many actions that should be taken to make our country more safe and secure. However, achieving a battle-ready public health defense at the federal, state and local levels will take years of sustained commitment, funding and oversight.

To stop the hemorrhaging of the nation's public health infrastructure and to achieve the optimum all-hazards approach to public health preparedness, TFAH recommends that Congress take the following actions:

- Despite a number of reports suggesting that states are only modestly better prepared to handle a terrorist attack, CDC funding for state and local preparedness capacity is in danger. The Secretary of Health and Human Services has informed the House Labor Health and Human Service (LHHS) Appropriations Subcommittee that he intends to redirect $55 million dollars, that had been allocated previously to state and local bioterrorism preparedness efforts, to support instead targeted improvements in 21 specific cities and the U.S Postal Service Strategic National Stockpile initiative. Under the proposal, almost every state will sustain a cut of over $1 million.

To protect all Americans, TFAH believes that there is a need to increase funding to enhance the readiness of targeted cities, while maintaining key CDC bioterrorism preparedness programs. However, we do not believe that the Cities Preparedness Initiative should jeopardize the health and security of the rest of the nation, especially since report after report indicates the country is still underprepared. The House Appropriations Subcommittee on Homeland Security denied a similar request to reprogram fiscal year 2004 funds away from the Department's Metropolitan Medical Response System (MMRS), and we hope that the House LHHS Appropriations Subcommittee will follow suit and continue to fund the state and local preparedness grants at their appropriated levels and find additional dollars to fund the CDC's Cities Readiness Initiative.

- In addition, the CDC's fiscal year 2005 budget for state and local bioterrorism preparedness programs is slated to receive an 11 percent cut or a $105 million reduction. Even in this tight fiscal year, Congress must restore the fiscal year 2005 funding; otherwise further readiness efforts at the state and local levels will be derailed. TFAH recommends that Congress make a long-term investment in biosecurity and authorize an independent review to determine whether current expenditures are sufficient. Experts note that at a minimum, the nation requires a $1 billion annual commitment for the next several years in order to achieve the appropriate level of biosecurity.

To assure that this investment is well-spent, CDC, in consultation with state and local health officials and outside experts, including those from other federal agencies like the Departments of Defense and Homeland Security, must define measurable standards for comprehensive preparedness that all state and major local health departments should meet.

- The Administration and Congress have addressed bioterrorism threats by developing and funding innovative programs such as Bio–Sense, BioShield and BioWatch. TFAH remains concerned that there is no overarching federal "BioGame Plan." We worry that there are overlapping jurisdictions, lack of coordination among various federal agencies, and no plan for intra—and interagency training or rapid deployment of resources in the event of an attack. Congress should identify a lead agency to develop and oversee a comprehensive BioGame Plan that clearly delineates the roles and responsibilities of each federal agency and its state and local counterparts.
- The President, in consultation with Congress, should convene a White House summit that will develop a concrete vision for the future of the American public health system and the resources needed to make it a reality. This summit should consider how our country can build a robust, integrated public health infrastructure. TFAH believes that such a summit could craft a blueprint for a public health system that is designed to meet both America's current and emerging health threats. The discussion must include how to develop a public health system for the 21st century—the summit should address all aspects essential to public health, such as bioterrorism, chemical, and radiological preparedness, known and emerging infectious diseases and chronic disease prevention and control. At the same time, we believe the summit should foster a long-overdue dialogue about the resources required to implement needed changes and guarantee accountability at every level of the public health system.

Terrorism thrives on uncertainty. We don't know when or where the next attack might be launched or whether it will be smallpox, Sarin gas or a small nuclear device. While we must continue to invest in defensive programs like BioShield, we cannot expect to vaccinate Americans against all threats unless we have a nimble, highly-trained, well-equipped public health defense that can rapidly detect, contain and respond to all health emergencies. That is the team work the United States needs. That is the team work Americans deserve.

Once again, thank you for allowing Trust for America's Health the opportunity to contribute to the policy debate on homeland security and public health. I am happy to answer any questions.

Mr. SHAYS. We will start out with the Ranking Member of the committee, Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman.

Dr. Hearne, you certainly articulate one of the greatest problems that we have in terms of dealing with bioterrorism, and that is that we don't have the public health infrastructure to really respond. One of the administration's programs that was announced in late 2002 was this national effort to vaccinate 500,000 health care workers for smallpox, and that was supposed to be followed by the vaccination of 10 million first responders.

We know we are 18 months away from the announcement of that program, and neither of those goals have been anywhere near achieved. I think there is about 40,000 or so people that have been vaccinated under the program, and there may be various reasons for it. But bottom line is, do you think we are prepared to deal with an attack of smallpox in this country? I know we heard Secretary Thompson say he thought we were prepared. And are we prepared to deal with an anthrax attack in this country? And can we distribute a stockpile that they tell us is out there in the event there is such an attack?

Dr. HEARNE. These are challenging issues, and certainly frightening ones to discuss and talk about. We are better prepared, and in the event of a smallpox, anthrax, or even an unexpected event—because that is the reality of terrorism, you don't know what is going to be thrown over the transom—we have seen some important improvements.

I do think in the specific instance that you asked with smallpox, we probably are a bit more vigilant. We would catch it early, which is really the most critical part of smallpox. We are not in a position or a policy to be able to vaccinate the entire country. We must pick it up quickly and do that ring inoculation, try to squeeze and contain smallpox.

Could we do as good a job as we should? I don't think so. I suspect we would have far more cases than if we were fully prepared as we should be, and that is where we need to see these stronger investments. We don't know where a smallpox would hit. And while you might want to target certain cities and heighten that capability, the reality is we need to have that vigilance across the board and improve our ability to rapidly respond at all levels in this country, and that has not been a priority and a response that we have seen yet today at the level that we would like.

Mr. TURNER. So is the answer yes or no? Could we respond adequately? Are we anywhere close to being adequately prepared to deal with even anthrax?

Ms. HEARNE. We are better prepared for anthrax. You want a yes or no? Not yet. We would do our best, and it would be certainly better than it was pre-9/11, but it is not as good as it should be.

Mr. TURNER. Do you have any indications that the administration is going to request the kind of funding that you believe would be necessary to get us prepared to deal with either anthrax or smallpox?

Dr. HEARNE. Let me make a very important point. Public health probably is the weakest link in homeland security today, and public health has also been the Cinderella issue of this country for over 20 years. This has been benign neglect, really, by many administrations. And recently this has been the most critical investment that we have had in public health in, as I have noted, decades.

Is it enough? No. And part of the issue is that it needs both a sustained and long-term commitment, but it simultaneously needs to have a much better set of performance measures and accountability so that people can be in a better position to answer those questions that you are asking, Mr. Turner, are we better prepared, where are our gaps, and what do we need to do? And that comes with not just money, but it also comes with the accountability metrics that are long overdue.

Mr. TURNER. Dr. Winegar, is project BioShield an adequate response to the bioterrorist threat?

Dr. HEARNE. It is one piece of the triad here. You know, as my testimony was pointing out, the ability to have drugs as a countermeasure are invaluable, but without the ability to deliver or have the brains at the head of the system that can both pick up an event and can rapidly determine who needs what, how to cover our population, it really doesn't matter what drugs you have, because those will be wasted countermeasures without the ability to do right and adequately protect the public's health.

Mr. TURNER. Dr. Winegar.

Ms. JOHNSON-WINEGAR. I agree that certainly BioShield is one component of an overall strategy, but as a stand-alone effort, it is not enough. And I wanted to reiterate the comment that I made before. I still think that there is a gap between the work that is going on as basic research and the procurement of items, and, as I have understood the legislation, that indeed is procurement of items that are not licensed but that have the potential to be licensed. And I think that that is where there is a large gap that really needs to be addressed. And that is the appropriate types of animal models and the appropriate clinical trials that, if necessary, address pediatric populations, elderly populations, populations with individuals who have an immuno-compromised system or other health problems that may prevent them from taking a vaccine that may be perfectly acceptable for normal healthy people in a limited age range.

So I think it is a step in the right direction, but as a stand-alone, it is certainly not the end-all, be-all.

Mr. TURNER. Thank you. Thank you, Mr. Chairman.

Mr. GOODLATTE. [Presiding] I thank the gentleman.

It is my pleasure to recognize the gentleman from Connecticut Mr. ays.

Mr. SHAYS. Thank you very much. I want to thank both of you for being here. Dr. Hearne, it is, I think, a very important statement that you made that you said public health is the weakest link in our war against terror, and I just hope that that doesn't get lost on people.

I want to know, Dr. Winegar, if you agree as well. You no longer work for Defense now. You can be totally candid.

Ms. JOHNSON-WINEGAR. I have always tried to be candid with you, sir.

Mr. SHAYS. But you have no restraints, there are no restraints?

Ms. JOHNSON-WINEGAR. I think public health is one of the major elements of a comprehensive defense. To say that it is the weakest link is perhaps a bit further than I would like to go. And I would like to say that the whole area of biodefense has been the ugly stepchild for many years. I personally fought many, many battles within the Department of Defense to try to get us a sufficient amount of funding, and while we all know that funding isn't the total answer

Mr. SHAYS. But given what you said, it is the ugly stepchild, so is there anything more ugly? I mean, is there another issue—the weakest link means it is the weakest link. It may be relatively good or not, but it is the weakest link. What do you think is the weakest link if it is not this?

Ms. JOHNSON-WINEGAR. I think intelligence is the weakest link.

Mr. SHAYS. Okay, fair enough. Well, we have identified two pretty weak links. Okay. And thank you for that answer.

I want to ask both of you how you have the capability to match the threat. And before you respond to that, I want to know if you believe bioterrorism is a legitimate concern that our country needs to defend against. We will just keep going back and forth. I will start with you, Dr. Hearne.

Dr. HEARNE. Absolutely, it is a significant concern. We have already had a number of reminders of that. While they have not been major events, I don't think anyone on this

Mr. SHAYS. So the bottom line is yes?

Dr. HEARNE. Yes.

Mr. SHAYS. And, Dr. Winegar?

Ms. JOHNSON-WINEGAR. Yes, I agree.

Mr. SHAYS. Do you believe that we are matching—I think I know the answer to this—is the capability matching the threat? And I think both of you have said no, but let me ask this question: Does that say to you that this needs to be more than a 9:00 to 5:00 effort or an 8:00 to 6:00 effort, that it may need to be, you know, 24 hours a day until we get to at least a certain level?

And I will start with you, Dr. Hearne.

Dr. HEARNE. You are probably starting with me because I am nodding my head vigorously. Absolutely it should be 24–7. We had that lesson with public health agencies. People would call on a Friday evening to report a possible case. There was no one answering the phone. That has been a major change since 9/11. We have gotten our agencies up to 24–7, response capability, but simultaneously we are actually hearing stories now that with budget cuts both at the State and Federal level and also at some of the local entities, those actual 24–7 response capabilities are being threatened.

Mr. SHAYS. But how about the capability for making sure that we have the antidotes to certain biological agents?

Dr. HEARNE. The Strategic National Stockpile has enormously expanded and improved our ability to have readiness on that scale. The issue is with the stockpile being ready, are the States ready

to receive those materials and do the distribution that would be needed in a major event.

Mr. SHAYS. Well, we had testimony that said we are 2 to 3 years away, and under a really significant event, we may be 4-plus years away. So should we just decide that should be the time schedule, or should we speed it up?

Dr. HEARNE. We absolutely could speed this up, and it is really an issue of going back to my premise that this has been the weakest link, that it has been the Cinderella agency in most States. It has not been a priority. And given if this were put up higher on the radar screen and given the top level of commitment by key policymakers, you could turn around these gaps in a very rapid time period.

Mr. SHAYS. Thank you.

Dr. Winegar.

Ms. JOHNSON-WINEGAR. I absolutely agree, and while some of the comments that were made earlier on how fast a particular research project can proceed are constraints on time, I too am quite dismayed by the long periods of time, and I would like to go on the record as saying that my estimate of when we will have sufficient antidotes for clostridium botulinum is in the 10-plus years away.

Mr. SHAYS. Nine was what I had heard, and I was surprised that we were being told less. One of the dangers in the Department is they want people not to be afraid, but my view is since September 11th, we need to make sure that people are told the truth, and particularly Members of Congress so we are not—I am just interested—was I given 5 or 8 minutes? Ten minutes. Would you mind if I had 1 more minute? Do you need to get a plane?

Mrs. CHRISTENSEN. Go ahead.

Mr. GOODLATTE. Without objection, the gentleman is recognized.

Mr. SHAYS. I wanted to just ask that last question, which I forgot. And it was my wrap-up question. So thank you. Just totally forgot it. Thank you for your kindness, Doctor.

Mr. GOODLATTE. I thank the gentleman.

It is now my pleasure to recognize the gentlewoman from the Virgin Islands.

Mrs. CHRISTENSEN. Thank you. I will see if I can get through this quickly, and then maybe Chris will remember his question.

But thank you for being here and for bringing the message that you bring, because we need some echoing of that message every time we talk about health and biodefense.

You know, I am concerned about the shifting of the funds from our everyday needs in public health to homeland security, which is obviously a priority and we need to ensure that we have the proper defense preparation, the ability to respond to bioterrorism. But the funding for public health preparedness in bioterrorism usually means—it has begun to mean taking away from some of the other functions. And given these concerns and our experience up to date, isn't it possible to not shift but make bioterrorism funding really dual use? What would either of you say about that and the approach that we should be taking?

Dr. HEARNE. Ideally, if we are smart on these investments, we do create a system that is all-hazards approach, whether it is a terrorist event or Mother Nature throwing the unexpected at us, like

SARS, like avian flu. You don't know what is going to hit, but they can all be of equal consequence.

You need to make sure that those investments are there, and, unfortunately, we have been shifting dollars, so that while we cover one flank, we are leaving our other exposed and quite vulnerable to unexpected events.

We are hearing stories all across the country of things like restaurant inspections. It may sound real sexy, but one that could be a form of food agricultural terrorism. But, two, it is a major event that goes on in this country that is preventable; and that is the bottom line if public health does its job. It is keeping people from getting sick in the first place, whether it is bioterrorism or those other everyday health risks.

One of the things that we ask is we shouldn't be robbing Peter to pay Paul here, and the cities initiative isn't a very important one. I don't mean to take anything away from it. It is just that we shouldn't be taking money from one place to the other when they are both underfunded as currently seen.

What in fact I think we really need to do here is stop for a moment and really take a look at we have not modernized our public health system really since the day it did its job back in the 1800s in stopping cholera and typhoid and yellow fever. Those were extraordinary investments that made a difference.

We are in a very different place today. We have got very different sets of threats. Anthrax or asthma, chemical weapons or cancer. We actually could have a much smarter public health system that could do its job in preventing all of those diseases much more effectively with probably not huge amounts of dollars, but we haven't set it up that way.

And in fact, one of the recommendations that we have in this report here is calling on Congress and the administration to host a national summit on modernizing, creating that 21st century public health defense, because there isn't a lot of money out there. But we could be doing a lot more, a lot better, smarter, safer, swifter, and we just need to take that time out and figure out how to put those pieces together, because there is a win here. We are just keeping it off the radar screen.

Mrs. CHRISTENSEN. Did you want to add anything?

Ms. JOHNSON-WINEGAR. I certainly agree with those points, and I would like to call your attention to the fact that many of the things that are on the threat list or thought of as bioterror agents also occur in other ways, and I will go back to Congressman Shays' example of botulinum toxin. Botulinum toxin is found in food poisoning, and we need to leverage what we have learned about treating those types of cases and diagnosing them and apply that to the use of the toxins as a biothreat. Now, of course there are going to be differences, but I think there needs to be a much greater collaboration and leveraging of the work that is done in the endemic disease, the emerging infectious diseases, with those things that are in the bioterrorist realm.

Mrs. CHRISTENSEN. Thank you. You know, when we visited several sites around the country and talked to first responders, several who had done exercises in responding to a simulated terrorist threat, we didn't find that public health and hospitals were really

fully a part of the first responder team, and I was wondering what are you seeing.

Dr. HEARNE. That may be one of the areas of most improvement out there. We hear across the board that for the first time ever, public health leaders know who their counterparts are in Homeland Security, in law enforcement, even EMS, which is a little surprising, you would have thought.

Clearly, though, there is also room for improvement. We have been hearing surprising reports. The RAND Institute, for instance, just put out a report a few days ago that looked intensively in California and actually found that public health departments knew their minority populations less than the police departments.

Now, what was interesting—we can take that a little further, but one of the things that was coming out of that is that public health has actually not been as engaged with disadvantaged populations as it could be and should be and particularly in the event of a bioterrorism outbreak, that the lack of those connections to key populations may be a significant problem.

So while there have been some very interesting new connections being made, some of the basic arenas that public health has been presumed to be doing well actually need to be improved.

Mrs. CHRISTENSEN. Thank you. And I thank you for alluding to the issue of minority populations, which I am sure you know is one of great concern to me.

Thank you, Mr. Chairman.

Mr. GOODLATTE. I thank the gentlewoman, and it is my pleasure now to recognize the gentlewoman from Texas, Ms. Jackson-Lee.

Ms. JACKSON-LEE. I thank the distinguished Chairman, and I thank the committee for this hearing. I laid out a scenario in the previous panel, just to suggest that all of us can do well by taking what we are doing more seriously, and I appreciate the work of both of you on this issue and the years of commitment.

My relaying of the anecdotal story regarding the pronouncement of the Attorney General was just to suggest that I think that 99.9 percent of Americans went about their daily business; and it is twofold, probably a tribute to how far we have come and what Americans believe we have done on their behalf. And maybe the other point is the lack of completeness in understanding of how much more we need to do.

So I think these hearings are important, because if Congress has any role it is oversight, and sometimes our oversight is not pretty. It has to be probative. It has to be provocative. And I say that because I want to compliment the Texans who were engaged in the work of dealing with the tularemia, and I don't want to take anything away from them, because Texas certainly has the advantage of having the likes of the Texas Medical Center. But also there are rural aspects of Texas that are not connected to such a fine network that is found maybe in Harris County, Houston, Austin, where the head of the Department of Health is, and of course connected to the Texas Medical Center.

So here is my point of questions, and I want to use, Dr. Hearne, your statement, and I would welcome the input of both of you. But my question goes back to the example of smallpox and the fact that we need to have—if we use that as an example, if I understand,

you are suggesting that we need public health officials. We need to have astute clinicians to notify public health officials, or disease surveillance systems capable of detecting possible smallpox. We need labs that can rapidly test to confirm smallpox cases. We need deployment of rapid response teams who can deduce, and we need a working pharmaceutical network as well.

There are many elements that I am concerned that, although good intentioned and we have made progress, I want to be provocative, I want to be piercing, because we will have no time to be that in time of crisis, and I do believe that we are still geared to looking for the airplane coming into our neighborhood. And we hear the word bioterrorism, we hear the word radiological attack or a chemical attack. I am not sure if we fully comprehend. And if we comprehend it in Texas, if I might use this as a laboratory, it is only because we live with refineries, and we live in what has been labeled the oil capital of the world. We have lived with natural gas and oil for many years. We have lived with our refineries and their fires, but no one can comprehend what it means to release a dirty bomb. No one can comprehend a purposeful attack on those refineries, short of an accident which is what you are used to.

So what I am trying to determine, we have made advancement in legislation that was passed soon after 9/11. We are now dealing with BioShield. I am not comfortable in even what we have gotten out of this hearing, with all due respect and appreciation of our fine public officials in Washington. I am not comfortable that we have a circumstance, if you will, that—or a set of circumstances that really have given us standards, has a network that is connected. Maybe I am connected in the fourth largest in the Nation. I am lucky, but I might be not be connected in a poor neighborhood in the fortieth largest city in the Nation, and I may not be connected 50 miles down the road, which turns rural as soon as you leave outside of the borders of Houston, you are in rural Texas.

So if you can give me the bad news and the roadmap to get from the bad news to where we are—and I know that some members already asked that—that would be helpful to us, because I just think that we are treading light waters and being polite. And let me just say, not criticizing any of the witnesses, because you have been forthright, but give us a roadmap of where we need to be going and who we need to be touching on these issues.

Dr. HEARNE. It is hard sometimes to tell the truth. Mr. Turner was trying to get me to say, yes or no, are we prepared? I don't particularly like sitting in this hot seat, having to—.

Ms. JACKSON-LEE. We will give you immunity. How about that?

Ms. HEARNE. If only it would cover smallpox and—here's the reality. We have a long ways to go. Your home State, Texas, if I remember right, scored 4 out of our 10 indicators. You can go back and take a look at where those gaps are, and there is a lot of work to be done in Texas, things like there is not sufficient laboratory capacity, there aren't enough workers. In fact, the budgets have been severely cut of the Texas Public Health Department. They tried to shut down their cancer registry and their birth defects registry. Birth defect is the number one cause of infant mortality in that State. That is just an example of the challenges that have been going on in that health department, let alone having to think

about bioterrorism. It is not pretty what has been going on on a lot of these fronts, and it is an issue of priorities and care.

But your question, in part, was you play the role of oversight and your job is to ask those tough questions and to make sure things are being covered that people may not always want to talk about.

Well, one of the issues, to push back to the table of the panel before, of Federal authorities was where are those measures accountability. Dr. Raub mentioned, as an example, they had a metric of 1 epidemiologist per 500,000 people. Well, they have never actually collected that information. HHS and CDC does not know if there are now 1 epidemiologist per 500,000, and in fact the benchmarks that HHS were producing aren't the ones that CDC are going to put out, but CDC still hasn't put it out and we are 3 years out in this bioterrorism program.

Accountability has not been the strongest suit of these types of issues, and it actually has been one of the benefits of Homeland Security's partnership with HHS, is that it has brought a greater sense of urgency and push for accountability. But I actually think that this would be just the type of issue to turn back to Congress and say where are those measures, how are we matching up? And the reality is our group put out this report on its 10 indicators, because we were filling a gap to answer just the questions we were getting in every office on the Hill of, well, so how better off are we, and is our job done? Because many people do believe with this important investment that has gone on the last few years, that we are taken care of. But the reality is we have a very long ways to go. But we have not set up what are those targets, what are those benchmarks, and what does every citizen in this country have the right to anticipate in terms of the protections and preparedness that they should have.

So I in some ways would appreciate to turn that back to Congress and to have that oversight role. It would be extremely helpful, because I think there are some significant cultural quality changes that need to take place in how we do health protection, and I am talking about the public health side in this country which has not had oversight, and it hasn't had really anyone caring about it before. And that is long overdue.

Ms. JACKSON-LEE. So your solution, or at least your suggestion, is that we intensify our oversight hearings and begin to probe into the State's structure or begin to probe HHS as to the accountability standards? Because I guess I am still looking for the list of accountability standards. Can someone point to me, can I go to the Web page, can I go somewhere and see their accountability standards, besides the very fine work that you have done? Does the government have an assessment on Iowa or Georgia or Mississippi or Texas or New York in terms of where they are? And then say categorically, you know what, they are at zero; they are not even talking to each other; we have got emergency relief for that State that is at zero, because that is where homeland security is?

Dr. HEARNE. No.

Ms. JACKSON-LEE. That is—.

Dr. HEARNE. Soon to come. But we have been hearing that for over a year now. There are benchmarks of expectations, but there are not performance standards set yet. CDC is in the process right

now of—after several iterations, is trying to develop those performance standards. It is currently piloting those performance standards in, I believe, five States and hopes to roll them out soon; but, again, we are at a point where the States are waiting on their 2004 guidance and still hasn't gotten it. And we are here in June of 2004.

Again, let me just—just to give a sense, public health is not rocket science. There are some very basic things that we have been doing since the 1800s but we are just not doing very well anymore. To set those benchmarks is critical but we need to have the impetus and energy and push to make sure that we are achieving those and that that accountability and commitment to hitting those marks are there.

Ms. JACKSON-LEE. Thank you. So oversight is crucial. Thank you.

Chairman COX. [Presiding] The gentlelady's time is expired. Dr. Hearne, Dr. Johnson-Winegar, I just have one question for each of you. Dr. Hearne, earlier we went into BioWatch; the BioWatch program, to oversimplify, starts with EPA collection, moves on to CDC analysis, and then, if necessary, to FBI investigation. There are other moving parts, but that is the superstructure.

And I want to ask whether, Dr. Hearne, you think that this is an appropriate role, particularly assuming that it grows in terms of scope and complexity for EPA.

Dr. HEARNE. I should probably confess my training is actually as an environmental toxicologist.

Chairman COX. Your focus on these areas is the reason I ask you this question.

Dr. HEARNE. One of the problems that we have right now in this arena is that there are many different agencies, many different programs evolving, developing, and unfortunately there is an enormous lack of coordination and clear authorities.

This is one of those areas that both has the challenge of where it fits, but I also would raise the issue of the concerns of the investments in BioWatch, in part that many people from the laboratory community have grave concerns about, is the best investment given the high rate of false positives and that the technology is not particularly accurate and ready to be rolling it out, because the number of false positives activate a very expensive and very costly response mechanism. And so one of the challenges has been that each time a sensor picks up a potential hit, its disconnect with the public health community starts and activates a very large response that overwhelms the system.

It is not working particularly well right now, and it is an issue that needs to be given more thought and more counsel, in part because we hear from so many points in the public health system about their concerns on BioWatch.

At the same time, this is the challenge; we need to have these new technologies but as currently configured, BioWatch does not appear to be a highly effective program.

Chairman COX. Given that the program itself has its own challenges—and take that as a given—is the structure of it, with EPA as collector, an appropriate structure from EPA's standpoint?

Dr. HEARNE. Well, I am sure EPA would say yes. Given—those were all systems that were originally designed and are still being

used for air monitoring systems across the country for a set of air pollutants that EPA is actually by law required to be collecting.

So those are units that are already in place throughout the major metropolitan areas collecting information. It is an idea that is smart in terms of it is building on an existing infrastructure rather than trying to reinvent the wheel. So, as such, it makes sense that it has been built on EPA.

The problem is it has been done in a vacuum from the public health and responders who need that information.

I guess it comes back to really the issue I brought up before of we probably need to take that time out and take a look at how all these different pieces most effectively can work together and how we can have a smart and strategic public health response rather than piecemeal parts spread out across the jurisdictions.

Chairman COX. Thank you, Dr. arne.

Dr. Winegar, I want to ask you with respect to bioterrorism research in general what you think is the appropriate role down the road for DOD, and how do we ensure that the expertise that is resident within DOD is integrated with all else that is going on, that it is not lost in this process? And what do you see as the primary role for the Department of Homeland Security, given that they won't be doing basic human health research?

Ms. JOHNSON-WINEGAR. Well, as was mentioned earlier, I think there is a role for everybody to play. DOD has traditionally been the leader in the area of biodefense and bioresearch. And while the individual scientists working at the bench probably can do equally good work for the Department of Homeland Security or the Department of Health and Human Services as he or she can for the Department of Defense, it would certainly help everyone, I think, to have a consolidated approach and clear leadership in the area. And I fear that what we have right now is fractured leadership, with the Department of Homeland Security having the lead in some areas while deferring the lead to HHS in the areas of medical countermeasures and then HHS needing to collaborate and communicate with DOD.

It is very confusing to the researcher in the field, whether they are in academia or private industry: Do I go to talk to Homeland Security, do I go to talk to NIH, do I go to talk to the DOD? And basically what is happening is that people are making the rounds and going to all of those agencies and waiting for somebody to step up and say, yes, this is what we are going to do; or, no, this is not what we are going to do. It is confusing to the public and to the research community at large, I feel.

Chairman COX. And if you were free yourself to heal the fracture, who would be in charge?

Ms. JOHNSON-WINEGAR. I think it has to be at some level above all the departments, and so that in my mind clearly points to the Homeland Security Council or the White House or some other body that sits above the individual departments.

Chairman COX. And is that true for operational decision making as well?

Ms. JOHNSON-WINEGAR. I think that is important, yes, because there are individual components that each of those departments will be asked to execute, and they can't do that in a vacuum. And

while I will agree that they are making progress, they still need some leadership in that whole area, I think.

Chairman COX. So if I understand your testimony, you would recommend that the Homeland Security Council be given line management authority over all of these Cabinet departments?

Ms. JOHNSON-WINEGAR. At least for the interim, until things are more established. And I think, in addition, the Homeland Security Council needs to be augmented. It is my understanding that in the whole area of bio, you can count the number of people on one hand.

Chairman COX. All right. I appreciate very much your straightforward answers to my questions and appreciate very much your expert testimony to our panel, and with that, I would excuse this panel and adjourn our hearing. Thank you very much.

[Whereupon, at 4:15 p.m., the committee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE RECORD

QUESTIONS FOR THE RECORD FROM RANKING MEMBER JIM TURNER FOR DR. PENROSE C. ALBRIGHT'S RESPONSES

National Biosecurity Analysis and Countermeasures Center

1. What is the mission of the National Biosecurity Analysis and Countermeasures Center?

Response: The National Biodefense Analysis and Countermeasures Center (NBACC) is the name of a facility proposed to be located at the National Interagency Biodefense Campus at Ft. Detrick, MD.

NBACC will provide the nation with the scientific basis for awareness of biological threats and attribution of their use against the American public.

NBACC will be comprised of two centers to execute this mission:

• The National Bioforensic Analysis Center (NBFAC) will provide national capability to conduct forensic analysis of evidence from bio-crimes and terrorism to attain a "biological fingerprint" to identify perpetrators and determine the origin and method of attack.

• The Biological Threat Characterization Center (BTTC) will conduct systematic and rigorous research to understand current and future biological threats, assess vulnerabilities, and determine potential impacts to guide the development of countermeasures, such as detectors, therapeutics, vaccines, and decontamination capabilitities.

NBACC is part of the Department of Homeland Security's (DHS's) integrated national biodefense complex consisting of Plum Island Animal Disease Center (PIADC); two University Centers of Excellence, the University of Minnesota's National Center for Food Protection and Defense and Texas A&M University's National Center for Foreign Animal and Zoonotic Disease Defense; and the Biosecurity Knowledge Center (BKC). Since Dr. Albright's testimony, the BKC has been established at Lawrence Livermore National Laboratory to serve as a national data resource network enabling information sharing and threat and vulnerability analysis, including results of research conducted at the NBACC facility.

2. How does it fit into the "Biodefense for the 21st Century" strategy announced by President Bush in April?

Response: The Presidential directive *Biodefense for the 21st Century* (HSPD–10) outlines four essential pillars of the nation's biodefense program. The four pillars are: threat awareness, prevention and protection, surveillance and detection, and response and recovery. The Department of Homeland Security has a role and responsibility in each of these four pillars of the national biodefense program.

The two programs executed at NBACC will directly or indirectly support each pillar.

The National Bioforensic Analysis Center was specifically designated in *Biodefense for the 21st Century* as "the lead Federal facility to conduct and facilitate the technical forensic analysis and interpretation of materials recovered following a biological attack in support of the appropriate lead Federal agency."

The Biological Threat Characterization Program will provide the scientific basis to characterize biothreats as called for in the Threat Awareness section of President Bush's directive which states, "We are building the flexibility and speed to characterize such (biological) agents, assess existing defenses, and rapidly develop safe and effective countermeasures."

3. How will NBACC interact with the intelligence community? Will the NBACC and the CIA develop concurrent threat assessments? How will conflicting assessments be prioritized?

Response: The primary conduit for NBACC interaction with the Intelligence Community is through the Information Analysis organization within DHS's Information Analysis and Infrastructure Protection (IAIP) Directorate.

While NBACC's mission is not to produce intelligence assessments, NBACC will support the intelligence community by conducting scientific studies and analyses to address gaps in our knowledge of current and future biological threats. As appropriate, NBACC will also work with operational directorates within DHS (such as those within IAIP) that are responsible for disseminating vulnerability data and best practice information to industry and to members of the protective community.

4. Which agency will be "in charge" of developing bioterror threat assessments?

Response:

As described in *Biodefense for the 21st Century,* the Intelligence Community is directed to "collect, analyze, and disseminate intelligence."

NBACC will support this mission by providing science-based analysis for characterizing the threat, assessing vulnerabilities, determining potential impacts, and attributing their use.

Plans for the NBACC include conducting science-based threat assessments of current and future biological threats. Center activities might include determining the feasibility of genetic manipulation of microorganisms to make them more harmful, and simulated "red teaming" or table top exercises using bioterror scenarios.

5. Can you provide us with a succinct list of activities that will occur in NBACC laboratories, including those associated with "science-based threat assessment"?

Response: The programs conducted at NBACC will provide knowledge of infectious properties of biological threat agents, potential means of employment against our nation, effectiveness of countermeasures, decontamination procedures, and forensics analyses so policy makers and responders can use this information to develop policies, programs and technologies to deter or defend against future attacks and save lives.

The Biological Threat Characterization Program will focus on:

(1) Developing systematic and rigorous methodology for risk assessment of biothreats.

(2) Conducting targeted research and laboratory studies to address specific knowledge gaps.

(3) Investing in infrastructure and procedures to support long-term biodefense programs.

6. Will this work involve the study of genetically-engineered pathogens and techniques for making existing pathogens resistant to antibiotics and vaccines, more virulent, or otherwise more dangerous? How will this work be overseen to ensure it does not violate our international treaties against biological weapons or pose a safety concern?

Response: The national biodefense effort across the U.S.Government is focused on understanding the potential impact of and defense against a terrorist use of biological agents.

The Biological Threat Characterization Center's mission is to provide science-based analysis for characterizing the threat, assessing vulnerabilities, and determining potential impacts to guide the development of countermeasures. Research and laboratory studies will be targeted to address specific knowledge gaps. This may include directed studies to evaluate the potential consequences of specific genetically-modified pathogens that exploit resistance to antibiotics and vaccines.

All work conducted by the BTCC will be for defensive purposes, as permitted by the Biological Weapons Convention (BWC), and will be consistent with existing U.S. policy and law.

The BWC compliance review process will be transparent within the U.S. Government and coordinated with other Federal agencies, including the Department of State to assure appropriate international authorities are advised of BTCC activities as they become relevant to international interests. In addition, criteria developed by the National Science Advisory Board for Biosecurity, and will be considered as appropriate.

The Department of Homeland Security is developing formal processes to review critical aspects of proposed projects for the BTCC, including technical, safety, ethical, policy, and legal issues. This includes plans to engage a standing committee within the National Academy of Sciences to advise on the technical and scientific aspects of its programs.

According to the Homeland Security Act, HHS is to work collaboratively with DHS as it sets goals and policies for medical countermeasures development. You have indicated in your testimony how this is occurring. DHS is also working with USDA on developing veterinary medical countermeasures to counteract agroterrorism.

7. Can you describe the difference between how these two inter-agency countermeasures research programs are managed, and whether one is working better than the other?

Response: The management for both medical and agricultural countermeasures share a common programmatic framework, as strategic and budget planning for both programs is the responsibility of the Biological Countermeasures Portfolio within the Science and Technology (S&T) Directorate of DHS. S&T also has a major role in inter-agency coordination, which includes efforts in a number of venues that were mentioned in the testimony before the committee (e.g., several Homeland Security Presidential Directives, Counterproliferation Technology Coordinating Committee, WMD-Medical Countermeasures Committee, National Strategic Plan for Homeland Security Science and Technology, etc.). Implementation and execution of individual program elements in S&T is the responsibility of either the Office of Research and Development (including NBACC, national laboratories, University Centers of Excellence), the Homeland Security Advanced Research Programs Agency (competitively awarded programs to the private sector, federal laboratories, and universities), or the Systems Engineering and Development (e.g., operational programs such as Bio-Watch).

The principal difference between how the two inter-agency countermeasures programs are managed is an operational difference. As specified by the Homeland Security Act of 2002, DHS S&T assumed responsibility ('facilities and liabilities') for the Plum Island Animal Disease Center in June 2003, and collaborates with the U.S. Department of Agriculture (USDA, Agriculture Research Service, and Animal and Plant Health Inspection Service) on a joint strategy for the study of foreign animal diseases (e.g., foot-and-mouth disease). DHS S&T and the Department of Health and Human Services (HHS) collaborate on determining medical countermeasures but DHS S&T does not have operational responsibility for any biomedical facility.

Both collaborative programs are working well in accordance with each agency's roles and responsibilities; there is no basis for stating 'whether one [relationship] is working better than the other.'

According to the Homeland Security Act, HHS is to work collaboratively with DHS as it sets goals and policies for medical countermeasures development. You have indicated in your testimony how this is occurring. DHS is also working with USDA on developing veterinary medical countermeasures to counteract agroterrorism.

8. Can you describe the difference between how these two inter-agency countermeasures research programs are managed, and whether one is working better than the other?

Response: Question 8 in the original transmittal of these Questions for the Record is a duplicate of Question 7 which has been answered above.

9. How do threat information and vulnerability assessments collected by DHS influence the research agendas, if at all?

Response: Threat characterization is an integral part of the S&T strategic planning process. This strategic planning process is informed by threat and vulnerability information available through the Intelligence Community, law enforcement, and other sources. S&T uses this threat information to identify knowledge gaps, against which research, development, test, and evaluation (RDT&E) needs are prioritized and translated into program execution strategies to fulfill operational end-user requirements.

For example, in the biological countermeasures area, S&T is leading a Biothreat Characterization Program for DHS, which will develop methodologies for a quantitative risk assessment process to understand biothreats, to perform targeted studies to address specific knowledge gaps, and to invest in infrastructure and procedures to support biodefense programs. The Biodefense Knowledge Center supports the Biothreat Characterization Program by collecting biodefense related information and expertise that is accessible on short time frames for immediate response, and longer time frames for strategic analysis and assessments.

The S&T Directorate is also engaged in understanding the broader threat environment. One new effort, denoted all-Weapons of Mass Destruction (WMD) Capability Assessment, is collecting and disseminating information on the capabilities of various terrorist groups, both state and non-state, to develop and deploy chemical, bio-

logical, nuclear, radiological, cyber, and explosives agents. This type of information will have a direct effect on establishing the research and development agenda of S&T.

A second activity, known as the Nuclear Assessment Program and transferred to DHS from the Department of Energy, has been analyzing communicated nuclear threats since 1977 for such agencies as the Federal Bureau of Investigation. Such information is now being used by our Radiological/Nuclear Countermeasures portfolio to help guide its research agenda.

10. Are NIH researchers and program managers given access to this threat information or allowed to set their own research agendas based on this information?

Response: Upper level NIH management, selected program managers, and selected researchers with appropriate clearances and the *need to know* are given access to threat information through a variety of mechanisms ranging from interagency working groups to various threat briefings. Examples of these interagency working groups include the Homeland Security Council/National Security Council-led BioDefense End-to-End Study and Counterproliferation Technology Coordinating Committee Studies, and the Weapons of Mass Destruction Biomedical Countermeasures Committee, a working group comprised of the Office of Science and Technology Policy, Health and Human Services, Department of Homeland Security, and the Department of Defense. This classified information, along with unclassified but highly relevant information on current and future threats, is then distilled by NIH management into an unclassified research strategy and priorities. This strategy is published to guide the activities of the broader NIH research community. For additional details on the process NIH uses to established research strategies and priorities, please contact NIH directly.

11. Right now there is no treatment for ricin exposure—once someone is exposed, they will die. And yet recent experience has shown that it is relatively easy to gather materials and transmit the toxin around the country. This is arguably a more serious threat than anthrax because at least anthrax has a vaccine and a course of treatment. So who has looked at this and determined it's not important to invest in a ricin treatment? How is this decided?

Response: Actually, there has been work done on developing a medical countermeasure for ricin exposure. The DoD completed efficacy studies in rodents on recombinant ricin toxin A-chain vaccine candidates and down-selected a lead candidate and an alternate. The Joint Science and Technology Office for Chemical-Biological defense predicts that a ricin vaccine candidate will be ready for transition to advanced development in FY 2006.

It seems that thus far our biodefense strategy has largely been driven by the nation's vulnerability to a mass-casualty attack, such as terrorist use of smallpox or a large airborne anthrax release. This is reflected in the categorization of agents on the A, B, and C priority pathogen lists from Centers for Disease Control—with smallpox and anthrax on the A list.

However, the anthrax letter attacks in October 2001 suggest we may need to pay attention to small- and medium-sized attacks, too. The Congressional Research Service has done such an assessment, and, interestingly, anthrax and smallpox were not at the top of the list. Instead, they determined glanders was the top concern, currently a category B agent.

12. Are you aware of this assessment, and, if so, what do you think of it? Does the current priority listing of pathogens need to be reassessed? Has it been reassessed? Who would be responsible for such a reassessment and when and how will it get done?

Response: Yes, we are aware of the Congressional Research Service (CRS) assessment. We agree that small and moderate size biological events also pose threats. However, more work would be needed to determine if the current priority listing of pathogens should be changed. As the CRS authors note on p. 53 of their study "The approach taken here is not the only valid approach, and different results may occur if different criteria and weighting systems are chosen." Also, an integrated national strategy must seek the difficult balance of responses and associated resource investments against the range of threats—from small scale events with more limited consequences to moderate-to-large scale events with extensive consequences. Efforts to date have been guided by threat prioritizations done by the Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD), and the Intelligence Community. Threat lists are not static and should be periodically reassessed to take into account new intelligence information, advances in science and tech-

nology, and changes in vulnerabilities and defensive concerns. Several such assessments are currently ongoing. The CDC is reassessing its threat priority list and DHS is conducting formal 'material determinations of threat" as part of the BioShield process.

In addition, DHS is required to provide a formal risk assessment every two years with the first due no later than January 2006. This will be a structured review process involving a broad range of intelligence experts, scientific experts, and analysts with 'vetting' before a still larger community.

Project Bioshield requires the Secretary of Homeland Security to make a Material Threat Determination before a countermeasure can be purchased. Such a determination process is now underway. The Secretary of Health and Human Services then determines how the threat should be addressed medically and whether an existing countermeasure program qualifies for a contract.

13. What is the process for making a material threat determination? How many have been completed to date?

Response: Material threat determinations are conducted by DHS to determine major threats as part of the BioShield process. These determinations draw on: available intelligence analysis of the intent and capabilities of potential threat organizations; on technical assessments of acquiring, producing, and disseminating the agents; and on systems analyses of vulnerabilities, potential attack scenarios, and resulting consequences of plausible attacks. These studies involve the relevant experts across the intelligence, scientific and analysis communities. To date, material threat determinations have been completed for anthrax and for botulinum toxin.

Anthrax Vaccine

14. What is the justification for a new anthrax vaccine (rPA) when there is already an FDA-approved vaccine (AVA) that has been used for years by the military?

Response: The current vaccine has a significant limitation with regard to manufacturing capacity (currently 6.6 million doses/year). Furthermore, limitations regarding the AVA vaccine have been articulated in the 2002 report, *Anthrax Vaccine: Is It safe? Does It Work?* from the Institute of Medicine of the National Academy of Sciences. The report concluded "that a new [anthrax] vaccine, developed according to more modern principles of vaccinology, is urgently needed." The new anthrax vaccine should be more readily produced and is anticipated to minimize some of the limitations associated with AVA.

15. Is it true that the new vaccine is similar to the existing vaccine in terms of safety, efficacy, and delivery? Please consider the purpose and results of the CDC anthrax vaccine safety and efficacy research program in your answer.

Response: AVA is licensed as a 6-dose (0, 2, 4 weeks and 6, 12, and 18 months) vaccine for pre-event only. The new rPA vaccine is anticipated to be a 3-dose vaccine (schedule to be determined) and will be licensed for both pre-event and post-event situations. There is no data at this time to indicate a difference in safety or efficacy. The CDC is supporting a study to examine whether the dosing schedule can be reduced and the route of administration changed, but that study will not be completed until 2007, although some preliminary data may be available later this year.

16. Please explain why the development and purchase of rPA for the stockpile is, at this time, a better investment than either a) purchase of AVA for the stockpile, or b) research and development of an oral or other advanced vaccine.

Response: Anthrax is a top WMD threat. There is an urgent requirement (as determined by the interagency WMD Medical Countermeasures subcommittee) for enough vaccine to protect 25 million persons. If we were to rely on AVA alone, at current manufacturing capacities, this could take over 20 years {(25 million people x 6 doses/person)/ 6.6 doses/year)}. The current manufacturers of rPA (under contracts with the National Institute of Allergy and Infectious Diseases) have facilities with capacities up to100 million doses/year and the current HHS Request for Proposals (proposals are currently under review) requires that delivery of 25 million doses be accomplished within 2 years of contract award. HHS awarded a contract on November 4, 2004 for 75 million doses of rPA. Delivery to the Strategic National Stockpile should begin mid-2005. It is likely that there will be a significant cost savings with rPA compared to AVA.

The U.S. Government recognizes the need for the development of a third generation anthrax vaccine with an improved delivery system that is more compatible with a rapid public health emergency response. However, delaying the acquisition pro-

gram until the development and availability of such a product is inconsistent with the national security environment.

The Administration has announced that the Department of Homeland Security will be leading the interagency effort to set national preparedness goals and ensure we will reach them.

17. Does DHS have the capability to complete this task for bioterrorism preparedness? How much work does it do with state and local health departments on a daily basis?

Response: The President's Biodefense for the 21st Century states "The Secretary of Homeland Security . . . is responsible for coordinating domestic Federal operations to prepare for, respond to, and recover from biological weapons attacks." DHS has a significant portion of the capability to provide this coordination and is increasing this capability where needed.

Public health biopreparedness and the associated interactions with state and local health departments is the primary responsibility of the Department for Health and Human Services.

QUESTIONS FROM MRS. KAY GRANGER FOR DR. PENSOSE C. ALBRIGHT

1. As your agency proceeds to support the development of WMD medical countermeasures, are you aware of, and what are you doing to support, the development and deployment of radiological and nuclear medical countermeasures?

Response: The Office of Science and Technology Policy (OSTP) National Science and Technology Council, Weapons of Mass Destruction Medical Countermeasures Subcommittee, Radiological and Nuclear Threat Countermeasures Subgroup is the advisory committee that is providing priorities and guidance to Project Bioshield in the area of anti-radiation drugs. Procurement of some such drugs may be authorized using funds from the Project BioShield appropriation, or funds of the Strategic National Stockpile, which is managed by HHS. DHS participates on this interagency group which is currently developing a national acquisition strategy. Additionally, coordination of research and development in the areas of both radioprotectants and radiation treatment drugs is taking place on many levels including the Counterproliferation Technology Coordinating Committee (CTCC). DHS supports the development of radiological and nuclear medical countermeasures by participation in the aforementioned activities but does not directly provide funding for development efforts.

2. Q01994: As follow up, are you aware of a product, 5-androstenediol, or "HE–2100," that is currently the lead candidate for the first radiation sickness drug, which has proven to repopulate bone marrow destroyed by radiation exposure? If so, what are you doing to help accelerate the approval and stockpiling of this or a similar drug for the protection of the American people and the military?

Response: A number of potentially effective drugs for use as radiological and nuclear medical countermeasures, including 5-androstendediol, have been brought to our attention. As discussed above, DHS S&T is supportive of the activities which lead to the approval and stockpiling of anti-radiation drugs. In the specific case of protection to the American military, the Armed Forces Radiobiological Research Institute (AFRRI) is charged with conducting research in the field of radiobiology and related matters essential to the operational and medical support of the U.S. Department of Defense and the military services. AFRRI has funded development and testing of 5-androstendediol and DHS S&T has been briefed on these results.

QUESTIONS FROM MR. BOB ETHERIDGE FOR DR. PENROSE C. ALBRIGHT

The Administration included $250 million for a Biosurveillance Initiative in its Fiscal Year 2005 budget request. Half of this project will be managed by the Centers for Disease Control, and the other half by the Department of Homeland Security. The Information Analysis Directorate is supposed to have major responsibilities, but I understand they have asked the Science and Technology Directorate to develop the systems they will use.

Response: The FY 2005 President's Budget asks for $129M in DHS to support the BioSurveillance Initiative. Of that $129M, $118M goes directly to the Science and Technology Directorate to: expand the BioWatch Program in the top threat cities; to pilot a BioWarning and Incident Characterization System (BWICS) in two of the BioWatch cities; to accelerate the development of next generation bio-detection systems; and to initiate R&D on biological detection systems for protecting critical food nodes. The remaining $11M of the $129M is to go to the Information Analysis

and Infrastructure Protection (IAIP) Directorate for the development of a National Biosurveillance Integration capability which will integrate state of health monitoring (human, animal, and plant) with environmental monitoring (air, agriculture, food and water), and with intelligence and threat data to enable the earliest possible detection of an event and to help guide the response to any such event. S&T has offered and is currently conducting the design study for this information system, which will be transferred to IAIP in FY 2005.

1. Has IAIP submitted this request to you, and when?

Response: By agreement of the Secretary's Office in February 2004, S&T is sponsoring the design of the National Biosurveillance Integration System (NBIS) to be completed in FY 2005. The statement of work for this system was developed through an interagency process. Quotations were reviewed by an interagency team and the design contract was awarded. A Conceptual Design Review was held in September, a Preliminary Design Review in October, and a Final Design Review in December, 2004. Actual implementation of the design will be transferred to IAIP in FY 2005.

2. When do you expect to begin working on DHS? plan for implementing the biosurveillance initiative?

Response: As noted above, the DHS role in the Biosurveillance Initiative consists of several elements, the planning for which has been on-going for sometime now. We are in the process of piloting the planned BioWatch expansion, with the pilot to be operational in New York City this fiscal year and with deployment to the other top threat BioWatch cities schedule for FY 2005 and early FY 2006. A systems design phase for the BWICS element was 'kicked off' this past summer. The additional funding to accelerate the development of the next-generation bio-detection program will be used to augment the 15 awards that have recently been made, or are in process, in this area. The requirements for the detection systems for critical food nodes are currently being developed through analysis of representative food contamination scenarios. And, we have awarded a contract for the design of the National Biosurveillance Integration System (NBIS) and expect to complete the design effort in December 2004.

3. Have you sketched out a role for state and local governments, or even the private sector, in collecting information? Is any funding set aside, to your knowledge, to include them?

Response: State and local governments play a significant role in BioWatch and BWICS and a significant portion of the funding in these programs will go to support them. The NBIS will integrate information streams provided largely by other Federal Agencies in their respective areas of responsibility, e.g., CDC will provide information related to public health, USDA to agriculture. NBIS may also employ data streams from other relevant sources.

4. Are you confident such a system can work?

Response: The Generation 1 BioWatch system has been operating successfully for over a year. The key elements of this Generation 2 expansion have been demonstrated in the laboratory and are currently being piloted. We are confident that they will work, though there will be the usual lessons learned to optimize their performance.

The National Biosurveillance Integration System is a new endeavor, with three main goals: to enable earlier detection of a biological event; to provide situational awareness to better guide the response to such an event; and, to facilitate the sharing of needed information at the Federal, state, and local level. To accomplish this, NBIS integrates new and emerging information streams from sector specific agencies. There is little question that combined access to these diverse information streams will significantly increase our situational awareness and improve the sharing of information to at all levels. That leaves the question of how much we can advance the detection timeline. Studies over the past few years, including analyses against historical data sets and limited field data have indicated that the use of non-traditional indicators (e.g. emergency room chief complaints) can significantly advance the detection timelines, as can the correlation of diverse events (e.g the linkage of dead crows with West Nile disease). Therefore, we fully expect that NBIS and the related sector sources will provide an advance in the detection timeline and that this advance will increase as we gain additional operational experience with various algorithms and data sources against real world backgrounds.

QUESTIONS THE HONORABLE JIM TURNER FOR DR. SHELLEY A. HEARNE

1. Do we have a coherent biodefense strategy today? How should we build one? What should the core elements be? How should its overall goals and objectives be set? What might they look like?

The Administration and Congress have addressed bioterrorism threats by developing and funding programs such as Bio–Sense, BioShield and BioWatch. However, Trust for America's Health (TFAH) remains conceed that there is no overarching federal "BioGame Plan." We worry that there are overlapping jurisdictions, lack of coordination among various federal agencies, and no plan for intra- and interagency training or rapid deployment of resources in the event of an attack. We believe that Congress should identify a lead agency to develop and oversee a comprehensive BioGame Plan that clearly delineates the roles and responsibilities of each federal agency and. its state and local counterparts.

The most important components of a national biodefense strategy for public health should include:

- Coordination among the agencies at the federal, state and local level to insure a clear delineation of duties and assure that system gaps are covered.
- State specific bioterrorism plans that are routinely exercised at the local, state and regional level with federal accountability for performance.
- All state public health laboratories must have minimum capacities to respond, 24 hours a day/7 days a week, to the full spectrum of public health emergencies, including terrorism, without compromising critical and routine investigations, such as testing drinking water or food supplies.
- Minimum standards for the public health workforce, including specific targets per capita for specialists (i.e., one epidemiologist/500,OOO people); training requirements and credentialing. With the growing workforce shortage, strategic federal investments in the public health workforce are required to protect the U.S. population from a wide range of health threats.
- Modem and up-to-date communications systems are vital. As we learned with anthrax and SARS, communicating with a shaken public is key to alleviating natural fears that arise with an unexpected threat or an emerging illness. The Health Alert Network (HAN), a federally coordinated system between the CDC and state/local health departments, has the potential to fill this current communications gap.

By using advanced technological tools, HAN will allow for real-time coordination in situations where even seconds matter. The HAN plays a vital role in the nation's state of readiness and timetables to completion and activation must be accelerated.

- Creation of a nationwide disease tracking command center at CDC. Because of the current "disease du jour" (i.e., SARS one month, and Monkeypox the next), CDC risks establishing dozens of different databases that are not directly linked or integrated, and may in fact, be redundant. This paradigm also limits the public health community's ability to understand the interconnections between diseases and possible causes. TFAH recommends that Congress provide the mandate, resources and support to establish a centralized disease tracking center within CDC. This would include tracking animalborne diseases, chronic diseases, such as cancer and asthma, events related to bioterrorism, and environmental risks.

Although there is agreement among public health experts on many of the core elements of a well-prepared public health system, there are still several critical goals and objectives that continue to need discussion. Accordingly, TFAH recommends that the President, in consultation with Congress and public health experts, should convene a White House summit that will develop a concrete vision for a 21st century American public health system and identify the resources needed to make it a reality. TFAH believes that such a summit should create a blueprint for a public health system that is designed to meet America's current and emerging health threats.

Specifically, the summit should address all essential public health concerns, including, bioterrorism, chemical, and radiological preparedness, known and emerging infectious diseases and chronic disease prevention and control. At the same time, we believe the summit should foster a long-overdue dialogue about the human and financial resources required to implement needed changes and to guarantee accountability at every level of the public health system.

Your organization's December 2003 report, Ready or Not? Protecting the Public's Health in the Age of Bioterrorism, found that "only two states are at the highest preparedness level required to receive and distribute. . .supplies needed to provide . emergency vaccinations and anti-

dotes." But my understanding is that every state has to submit a stockpile distribution plan to the federal government.

2. How accurate is this statistic? What is wrong with the state's plans? Are they unworkable? Haven't they been exercised?

The Department of Homeland Security (DHS) and CDC evaluate the states' Strategic National Stockpile (SNS) distribution capabilities and assign them a preparedness rating of red, amber or green. A red rating is the worst, while green is the best. In TFAH's report, "Ready or Not? Protecting the Public's Health in the Age ofBioterrorism," only two states had obtained green status as of November 2003. From recent public reports, TFAH has learned that an additional state (Louisiana) has now obtained green status, although our organization has not conducted a formal review. There are also unsubstantiated reports from government officials that several states have lost ground recently in their SNS status, but TFAH does not have specific quantitative information.

For TFAH's December 2004 state-by-state report on preparedness, we will attempt to update the SNS information. For up-to-date accuracy, TFAH would recommend that the Committee directly request CDC and DHS to provide a tabulated chart on the number of states that have obtained green, green minus, amber plus, amber, red plus and red status for the SNS.

States have developed SNS distribution plans, which are reviewed and . assessed by DHS through intensive on-site teams. DHS should be applauded for establishing performance standards and evaluation methods, which is an unusual practice in the public health field. The challenge states are facing in preparedness for stockpile distribution are numerous, ranging from lack of sufficient workforce to limited funds. As noted in our testimony, many states had planned on tapping their National Guard units for distribution, which may now be unavailable due to deployment in Iraq and elsewhere. In other instances, states have not done sufficient training or exercising with respect to stockpile distribution. There have also been complaints that as SNS responsibilities were transferred from CDC to DHS, there were significant delays in funding, guidance and the ability for DHS representatives to conduct evaluations.

You discussed in your testimony your concerns about a workforce sbortage in distribution of the stockpile. We understand that the Secretary's recent reprogramming request would include funding for 21 cities to employ the U.S. Postal Service to help disseminate antibiotics in the case of a terrorist event.

3. Can you discus the pros and cons of this approach? Given the traumatic experience of many postal workers during the 2001 anthrax attacks, do you think they are prepared or even wiling to take on a duty that might put them at risk?

By all indicators, this nation is unprepared on multiple levels for a major bioterrorism attack. One critical weakness relates to how to deliver vital medical materials, such as antibiotics, antidotes and vaccines, to large segments of the population. Almost all states fail to be fully prepared to receive the Strategic National Stockpile (SNS), in large part because of a limited distribution capacity. In TFAH's past reports, the enormous public health workforce shortage is cited as a major factor for this preparedness shortcoming. Rather than making an investment in revitalizing the diminished public health workforce, the Administration is proposing a unique strategy to tap into the U.S. Postal Service's delivery experience and network.

The "pro" argument for this approach is that it potentially provides officials with a vast delivery network that is well-organized and geographically familiar with the community. Given that many states had developed distribution plans relying on National Guard Units, short term alternatives are needed. But this approach has significant vulnerabilities, which again highlights the need for a national commitment to rebuild our public health workforce to sufficient levels, rather than relying on stopgap measures.

The concerns about relying on the U.S. Postal System during a bioterrorism event are multiple, particularly during broad scale quarantine/isolation. Public health and emergency response experts are gravely concerned about how the American public would respond during this type of crisis; fears range from distrusting government information/recommendations to civil unrest. Research, public opinion polls and past experience highlight that "trust" is the most critical factor influencing the public's response and that the healthcare provider community is the most trusted resource. In the midst of a major pandemic or bioterrorism event, response workers tasked with distributing . medical supplies to isolated/quarantined homes will need to be

far more than deliverymen, but instead will need to be well-trained, familiar with health issues and trusted.

TFAH cannot assess if U.S. Postal Service employees will be prepared or willing to travel to potentially contaminated locations. However, we would like to point out that even if provided with extensive training, individuals inexperienced with infectious disease may not respond rationally or well to a perceived health threat. The HIV/AIDS crisis is a vivid reminder that despite widespread information on the virus's transmission, many non-health care workers refused to interact with infected individuals. In addition to transporting critical medical supplies to homes, postal workers would be playing dual roles—providing information about the health emergency and giving assurance during a crisis. A family cordoned off from the world will inevitably have specific questions about possible symptoms, doses for children, elderly or immune-suppressed individuals, why isolation is necessary, etc. These front line responders need to be well trained in crisis management that builds on their fundamental health skills if a system of quarantine and isolation is to work.

A better short term option would be to consider a network of home health care providers, ambulance services, EMS and even pharmacists who have better fundamental training in health matters. Or at a minimum, a bioterror response plan should ensure that these health professionals are integrated into an emergency response system. But in the long term, a serious reinvestment is needed to refortify and bolster our nation's public health workforce.

If current workforce demographic trends are left unchecked, they will have an adverse affect on the capacity of state health agencies to carry out their mission; including responsibilities that have continued to expand since the events of September 11, 2001, and the ensuing anthrax attacks. Hiring freezes at the state and local levels, due in part to budget deficits and competition from higher-paying private companies contribute to the workforce shortages.

TFAH supports legislation that has been proposed to begin to address this critical public health need. The Public Health Preparedness Workforce Development Act of 2004 is designed to alleviate workforce shortages in federal, state and local government public health agencies. The bill establishes two new programs for students pursuing degrees in public health disciplines—a new scholarship program and a loan repayment program.

Examples of disciplines related to public health that would be covered by the legislation include: laboratory sciences, epidemiology, environmental health, health communications, information sciences, public administration, social work, and nursing.

Cuts in Preparedness Funding

4. If enacted, what will be the effect on bioterrorism preparedness of the $105 million reduction in state and local bioterrorism capacity grants?

The proposed funding cut of $1 05 million in state and local capacity grants, (11 % from fiscal year 2004 appropriated levels), will seriously erode state and local preparedness across the nation. The cuts proposed for fiscal year 2005 will be especially hard-hitting because, if enacted, the $105,000,000 reduction in state and local preparedness dollars would follow the Department of Health and Human Service's reprogramming of $55 million appropriated by Congress in fiscal year 2004 for bioterrorism capacity grants to the CDC Cities Readiness Initiative, Biosurvelliance Initiative and quarantine acceleration efforts.

The reprogramming of these funds has resulted in a reduction of $1.085 million for most states (please see attached chart of state-by-state cuts resulting from the reprogramming), which significantly weakens the ability of local and state public health officials to respond to a health emergency. For example, according to the Association of State and Territorial Health Officials (ASTHO), negative effects of the reprogramming request may include: reductions in workforce; delays in the creation of surge laboratory capacity; elimination of planning activities for the Strategic National Stockpile; cancellation of planned training events and statewide exercises for a potential chemical attack; and discontinuation of the implementation of the statewide Health Alert Network.

The proposed $105 million cut in fiscal year 2005 funding would be nearly' double that of that of funds that were just reprogrammed away from state and local capacity grants and the impact on public health agencies to respond to a bioterror attack would be even more draconian. That is why TFAH believes that even in these tight fiscal times, Congress must restore the proposed $105 million cut. Otherwise further readiness efforts at the state and local levels will be derailed. TFAH recommends that Congress make a long-term investment in public health preparedness and authorize an independent review to determine whether current expenditures are sufficient. Experts note that at a minimum, the nation requires a $1 billion annual com-

mitment for the next several years in order to achieve the appropriate level of public health security .

To assure that this investment is well-spent,CDC, in consultation with state and local health officials and outside experts, including those from other federal agencies like the Departments of Defense and Homeland Security, must define measurable standards for comprehensive preparedness that all state and major local health departments should meet.

The General Accounting Office has reported that no hospital funded through federal preparedness grants is able to meet the benchmark of serving a surge of at least 500 patients.

5. Why do we remain so far from effective mass casualty preparedness? What will it take to get our hospitals up to a minimum standard? What should that standard look like?

Based on input from the University of Pittsburgh's Center for Biosecurity, at present, most hospitals in the U.S. would have great difficulty dealing with 50 critically ill victims of a bioterrorist attack, let alone 500. As was evident in Toronto hospitals during the SARS outbreak last year, highly contagious diseases have tremendous impact on hospital function, and in fact, hospitals caring for SARS patients or victims of a bioterror attack with smallpox, for instance, would be more likely to experience a decrease in overall capacity, not an increase in capacity. Most hospitals have only the numbers of doctors and nurses they need for routine purposes. If more doctors, nurses paramedics, medical technicians, cafeteria workers, sanitation workers, etc., were needed in crisis, hospitals would need to have systems in place to bring on more staff from the community or elsewhere.

Further complicating matters, in an actual event, many hospitals may not be able to keep even their usual staffing commitments—regular health care workers may be fearful of going to work or of leaving their family members during such a crisis, or, as was the case in SARS, some may become ill themselves from the disease at hand. Serious and integrated planning would need to take place to create the kind of emergency staffing systems needed to keep hospitals up and running in the case of a bioterror event resulting in mass casualty.

Hospitals typically have sufficient medical supplies and ventilators to serve routine needs, no excess. While the Strategic National Stockpile (SNS) may be able to provide some of these key supplies to hospitals in the time of crisis, most hospitals do not currently know exactly what is in the SNS, how quickly or by what mechanism they would receive components of the SNS, how decisions would be made to allocate such components, etc. As noted earlier, few states have reliable systems to distribute components of the stockpile to hospitals.

Recognizing this vulnerability, Congress made important new funding commitments for hospital preparedness over the last few years. Unfortunately, these funds were divided across the hospital community throughout the U.S. without consideration for risk and need, thereby dangerously diluting the resources. Few U.S. hospitals have received serious funding to prepare for bioterrorism. One major hospital in New York City, located only blocks from the World Trade Center site, received $40,000 in funding last year to address all of its biopreparedness and terrorism preparedness needs. These days $40,000 would pay for about half of one senior nurse's salary.

Commensurate with this, hospital preparedness is treated in many communities as an avocation, with work done after hours by a dedicated few. To be able to cope with an event producing 500 or more victims, hospitals need to develop preparedness programs built on reliable systems that are testable, scaleable, and capable of "dual use" for meeting a full spectrum of challenges. This will require a sustained and more substantial funding stream with realistic guidance. Currently, HRSA guidance covers a broad range of initiatives, but present funding levels are unrealistic to accomplish few, if any.

One of the ongoing concerns that we have when trying to determine state and local preparedness for a terrorism event is our focus on biological readiness. Recent reports of a possible terrorism event seem to suggest that a dirty bomb or chemical attack, similar to the recent ricin attack in the Senate office buildings, are just as possible if not more likely

6. Do you think we are prepared for a chemical or radiological attack? If not, what do we need to do to become better prepard?

From a public health perspective, the U.S. is woefully unprepared for a chemical or radiological attack. With respect to chemical terrorism, a report issued by TFAH in June 2003 found that state public health laboratories are "dangerously unprepared" to fulfill their roles as first responders charged with identifying chemical

agents used in an attack. The report, "Public Health Laboratories: Unprepared and Overwhelmed," examined the capabilities of state public health laboratories, a crucial component of our defense and response system, and found that a majority of labs are in need of modernization and stabilized funding support. Labs are responsible for identifying the chemical weapons used in an attack, which then drives the critical treatment, containment, and clean up decisions. The report found gaps in planning, coordination, equipment, training, safeguards, workforce, and environmental testing capacity for chemical agents.

TFAH's recommendations for improving public health lab capacity to respond to a chemical or radiological attack include: .

- *Enhanced Capacity:* By the end of 2004, each state should have at a minimum, testing capabilities for priority potential chemical and biological weapons agents.
- *Modem Communications:* All state public health laboratories must establish an effective communications network incorporating clinical laboratories, hospitals and private labs that evaluate patients directly.
- *More Expertise:* Each state laboratory should have at least two trained PhD-level microbiologists and one PhD-level chemist to ensure effective biological, chemical and environmental testing capacity.
- *Enhanced Federal Commitment:* Federal funding for improving the readiness of public health laboratories to respond to biological, radiological and chemical attacks should be $200 million in fiscal year 2005. This level of funding is essential if labs are to have the ability to conduct clinical testing for potentially dangerous chemicals, such as ricin, cyanide, nerve agents and pesticides.
- *CDC Leadership:* CDC must have the authority to ensure capacity, collaboration and consistent methodology for clinical testing for chemical exposures. The National Center for Environmental Health should be supported to advance methodologies, develop a training system and establish performance measures for state laboratories. DHS should partner with CDC and Environmental Protection Agency (EPA) to prioritize chemical agents for environmental and clinical laboratory methodologies.
- *Joint Training.* Key federal agencies including DHS, EPA, and CDC should collaborate to develop a joint training exercise with states and first responders to prepare for chemical attacks. The May 12, 2003 "Topoff2" emergency response exercise had components to examine nuclear and biological threats, but did not include a chemical scenario. To date, there has not been a substantial training exercise to test national and local readiness in the event of such an attack.

Increasingly, there are some who see bioterrorism preparedness as a trade-off. That is, funding for public health preparedness for infectious diseases means less money for other functions, such as community health, elderly care or obesity reduction plans. Focusing on a new anthrax or tularemia vaccines means less of a focus 'on tuberculosis or malaria.

7. Are there concerns real? Given our experience to date, is it possible to make bioterrorism funding truly "dual-use?" What can we do better to achieve an all-hazards approach?

The tragedies of September 11 and the subsequent anthrax attacks shook the nation—and highlighted in the most dramatic way possible that our country was not ready to respond to large scale health crises. Even before the threats of bio—and chemical terrorism, the nation's state and local health agencies were already stretched too thin trying to manage everything from infectious disease outbreaks to preventing chronic disease like cancer and asthma, with too few resources.

Over the course of the last year alone, local, state, and federal health officials have responded—and contained—SARS, monkeypox, flu, and West Nile virus outbreaks, and the recent ricin incident in the Senate, while simultaneously working to prevent chronic diseases and address the everyday health needs of all Americans.

TFAH believes that rather than concentrating solely on bioterrorism or responding to each "disease du jour" crisis individually, public health preparedness efforts must be focused on an "all-hazards" or "dual-use" approach. This approach would focus on strengthening the fundamentals of our public health defenses, including laboratory capabilities and communications and response procedures.

To achieve the optimum all-hazards approach to public health preparedness, TFAH's specific recommendations include:

- CDC must formally authorize states to use federal preparedness funds to support an "all-hazards" approach to preparedness that simultaneously addresses the potential for biological, chemical, radiological and natural disease outbreaks.

- CDC, in consultation with state and local health officials and outside experts, must define measurable standards for comprehensive preparedness that all states and major local health departments should meet.
- Congress should provide long-term commitment and oversight toward ensuring the nation achieves adequate and sustainable public health security. As such, Congress should authorize an independent review to assess whether current expenditures—at the federal, state and local levels—are sufficient.
- Health security requirements must be established, including mandates and accountability measures to ensure all citizens are adequately protected.
- CDC must be required to track state and local funding and expenditures on critical public health functions, particularly those involving federal support. Unfortunately, there is mounting evidence to indicate that severe state budget cuts dilute the impact of the federal preparedness investment. Concerned that federal dollars should supplement—and not supplant—state and local funding streams, Congress urged the Health and Human Services Secretary to guard against such actions, but this "maintenance of effort" needs to be enforced.
- CDC should independently verify that health emergency performance standards are being met at the federal, state and local levels.

As stated earlier, that is why TFAH also recommends that the White House, in consultation with Congress, convene a national summit on the future of public health to develop a cohesive and proactive approach to public health protection.

The Administration has developed a Biowatch program, deployed in cities throughout the country, and a new Bio-surveillance initiative, which is to involve building complex new information systems both at DDS and at the Centers for Disease Control, known as BioSense. The concept of detecting a release as early as possible makes a lot of sense in terms of protecting the public. But DDS itself admits that the Biowatch system may be too costly and labor intensive. Some scientists have suggested the syndromic surveillance, the basis of BioSense, has not been proven to work.

8. Are these systems ready to be fielded, or do we need more research and to develop better systems first? Are the resources we are devoting to this system well spent?

The BioWatch Program is intended to provide early warning of a mass pathogen release, which inherently makes sense in light that human symptoms from bioterrorism may not appear for days after exposure. Numerous questions have been raised about the program's inherent efficacy, costs, the strategic siting of detectors, workforce needs and the overall ability to coordinate responses with the local public health agencies.

One major issue is the strategic location of the detectors. Building upon the nation's existing air quality monitoring system, the biopathogen detectors are reportedly combined with EPA's infrastructure for tracking ambient air pollutants, such as ozone and nitrous oxides. Efforts are underway to expand BioWatch to locations in all major metropolitan statistical areas, but these locations do not generally coincide with where a pathogenic agent would be released. For example, EPA's air monitors are positioned on large building rooftops and airport outdoor properties to capture ambient air pollutants. For terrorists with high impact designs, pathogens are more likely to be released in lower, more closely contained areas with dense populations. For early warning purposes, BioWatch may have greater value positioned in high target areas, such as subways, large arenas, and ventilation systems for significant or landmark buildings. Already, its limited applications come with a significant price tag: annual operating costs are estimated at $1 million per city, after the initial $1 million investment per location.

In addition, numerous laboratory issues abound with BioWatch. First, the pathogen monitors are highly labor intensive, requiring samples to be collected every 24 hours from the aerosol samplers and are analyzed using a polymerase chair reaction (PCR) technique. Lab capacity is already stretched thin in most state and local public health agencies. We speculate, that in reality, BioWatch results may take days to determine, raising questions about its early warning capacity .

9. Are these the best we can do in detection, or are there other options we should be considering?

Numerous federal and independent reports have noted the gaps in basic public health preparedness, from laboratory capacity to rapid response teams to disease surveillance systems. Significant improvements are needed in public health preparedness that far outweighs the potential benefits of the BioWatch programs. A cost benefit analysis for preparedness would most likely reveal that more lives would be saved by investing in state or the art disease surveillance systems, ade-

quate medical distribution systems, trained and sufficient numbers of public health workers, strong communications operations, and routine exercises for all hazards. While BioWatch is a technological advance, its limited coverage and high labor and resource costs, make it a questionable investment in light of greater bioterrorism preparedness needs.

At this stage, BioWatch is of limited value and should be revaluated in the context of the broader strategic needs of the nation's bioterrorism defense.

The rapid increase in funding for biodefense has led to the building of more biocontainment labs and many more researchers working with these dangerous pathogens. It seems that this could lead to a greater risk of theft or accidental release of these pathogens.

10. Are you concerned about the safety and security of these labs? Are we doing enough to ensure the safety and security of biodefense research in this country?

Although the safety and security of state public health labs is of concern, there are additional overarching issues with respect to the role of labs during a public health crisis. The nation's 2,000 state and local public health laboratories, together with hospitals and local health departments, would quite literally be 'front-line' defenders in case of a terrorist attack. In our 2003 study, TFAH found that 30 years of inadequate funding and the absence of federal oversight have rendered public health laboratories unable to respond appropriately to more traditional hazards, let alone acts of terrorism. An under-prepared workforce, a shortage of trained laboratorians, and old, often outdated facilities lacking the latest equipment, reagents and other tools, render public health laboratories dangerously unprepared to respond to a public health emergency. Public health specialists point out that, while the technologies and expertise exist to manage bioterror threats, laboratories lack the resources to access them.

QUESTIONS MR. ED MARKEY FOR DR. SHELLEY A. HEARNE

As you know, the only federal program that directly coordinates local first responders to deal with a bioterror attack is the Metropolitan Medical Response System. This program gives direct grants to 125 US cities to coordinate fire, police, hospital and public health officials for terror attacks with large numbers of casualties. However, the President's fiscal year 2005 budget contains no money for the program.

1. Do you agree with the Administration's efforts to eliminate MMRS?

2. How important in your opinion is coordination among local first responders—hospitals, fire, police and public health officials—in mitigating the effects of a' bioterror attack in an urban area?

The goal of Metropolitan Medical Response System (MMRS) is to support local jurisdictions by enhancing and maintaining all-hazards response capabilities with respect to a mass casualty incident, including but not limited to, a terrorist attack during the early hours. TFAH believes that the basic tenet of this program—enhancing the coordination of activities between the major players involved in responding to a mass casualty is critical and we applaud this coordination where it is working well.

QUESTIONS FROM MR. BOB ETHERIDGE FOR DR. SHELLEY A. HEARNE

You have called for the federal government to define measurable standards for comprehensive preparedness that all states and major local health departments should meet for preparedness. This is exactly what the interagency process the Department of Homeland Security is supposed to manage.

1. How would you advice the Department to accomplish this task? What would "preparedness" look like? How would we know we were prepared until something happened and we could measure our response?

Over two years after the state bioterrorism preparedness program's launch, at least three separate initiatives are underway throughout the federal government to establish performance measures for readiness for a major public health emergency. The Centers for Disease Control and Prevention (CDC) is in the pilot phase of testing evidence-based performance goals for states public health disaster preparedness. The Department of Health and Human Services (HHS) has separately been assessing potential benchmarks to evaluate state programs. The Department of Homeland Security (DHS) recently embarked on a comprehensive preparedness exercise which brought together experts representing a wide variety of the "preparedness" world including public health organizations. The goal of exercise was to create a "universal

task list" for states and communities. According to public health experts, the exercise was based on various scenarios that were not well designed because they failed to accurately reflect what would happen during a major health emergency. Throughout the exercise, goals and public health roles were uncertain within the context of the comprehensive preparedness initiative.

Unfortunately, states are implementing the third year of the grant program without overall preparedness standards in place. Further, it appears that DHS, HHS and CDC are not coordinating these efforts so that state and local health departments would ultimately have one set of measurable standards to abide by. TFAH would strongly recommend that the CDC and HHS directly coordinate a performance measure system for state and local preparedness, and subsequently build it in and test it through DHS's comprehensive preparedness effort. Using realistic biological, chemical or radiological scenarios, DHS could effectively test public health readiness with the CDC/HHS performance measures.

HHS Reallocation of $59.4 million in State Emergency Preparedness Funds for FISCAL YEAR 2004

State	CDC FISCAL YEAR 2003 Emergency Preparedness Funds	Dollar Amount of Cut to State	Percent Cut From FISCAL YEAR 2003 Funds	Redirected $ for Cities Readiness Initiative		TFAH BT Preparedness Score, Scale of 1–10**
Alabama	$14,056,645	-$1,085,000	-8%	.....	.....	6
Alaska	6,284,107	-1,085,000	-17	.....	.....	3
Arizona	15,755,035	-1,085,000	-7	Phoenix	$1,280,000	5
Arkansas	10,461,043	-1,085,000	-10	.....	.....	2
California	55,589,662	-1,085,000	-2	Los Angeles	2,670,000	7
.....	.....	.....	.....	San Diego	1,220,000	.....
.....	.....	.....	.....	San Francisco	940,000	.....
Colorado	13,979,790	-1,085,000	-8	Denver	820,000	5
Connecticut	11,960,524	-1,085,000	-9	.....	.....	4
Delaware	6,614,378	-1,085,000	-16	.....	.....	5
District of Columbia	11,162,901	.....	No Cuts to DC	DC	830,000	3
Florida	38,181,999	-1,085,000	-3	Miami	710,000	7
Georgia	22,034,847	-1,085,000	-5	Atlanta	740,000	3
Hawaii	7,486,672	-1,085,000	-14	.....	.....	4
Idaho	7,676,282	-1,085,000	-14	.....	.....	3
Illinois	24,923,148	-1,085,000	-4	Chicago	2,150,000	5
Indiana	17,416,386	-1,085,000	-6	.....	.....	4
Iowa	10,941,890	-1,085,000	-10	.....	.....	3
Kansas	10,476,095	-1,085,000	-10	.....	.....	3
Kentucky	13,245,815	-1,085,000	-8	.....	.....	2
Louisiana	14,059,595	-1,085,000	-8	.....	.....	5

HHS Reallocation of $59.4 million in State Emergency Preparedness Funds for FISCAL YEAR 2004—Continued

State	CDC FISCAL YEAR 2003 Emergency Preparedness Funds	Dollar Amount of Cut to State	Percent Cut From FISCAL YEAR 2003 Funds	Redirected $ for Cities Readiness Initiative		TFAH BT Preparedness Score, Scale of 1–10**
Maine	7,603,092	-1,085,000	-14	.....	.....	3
Maryland	15,915,365	-1,085,000	-7	.....	.....	7
Massachusetts	17,972,524	-1,085,000	-6	Boston	840,000	5
Michigan	25,278,581	-1,085,000	-4	Detroit	1,030,000	3
Minnesota	15,101,600	-1,085,000	-7	Minneapolis	710,000	5
Mississippi	10,795,501	-1,085,000	-10	.....	.....	2
Missouri	16,424,504	-1,085,000	-7	St. Louis	690,000	4
Montana	6,834,837	-1,085,000	-16	.....	.....	3
Nebraska	8,485,811	-1,085,000	-13	.....	.....	6
Nevada	9,251,219	-1,085,000	-12	Las Vegas	790,000	5
New Hampshire	7,552,202	-1,085,000	-14	.....	.....	5
New Jersey	22,248,528	-1,085,000	-5	.....	.....	5
New Mexico	8,710,551	-1,085,000	-12	.....	.....	2
New York	27,794,404	-1,085,000	-4	NYC	5,100,000	6
North Carolina	21,630,396	-1,085,000	-5	.....	.....	5
North Dakota	6,290,025	-1,085,000	-17	.....	.....	5
Ohio	28,082,405	-1,085,000	-4	Cleveland	770,000	4
Oklahoma	12,031,404	-1,085,000	-9	.....	.....	3
Oregon	12,039,235	-1,085,000	-9	.....	.....	3
Pennsylvania	29,933,326	-1,085,000	-4	Philadelphia	1,350,000	3
.....	.....	.....	.....	Pittsburgh	690,000	.....
Rhode Island	7,147,493	-1,085,000	-15	.....	.....	6
South Carolina	13,232,255	-1,085,000	-8	.....	.....	4
South Dakota	6,536,811	-1,085,000	-17	.....	.....	4
Tennessee	16,651,663	-1,085,000	-7	.....	.....	7
Texas	48,310,184	-1,085,000	-2	Houston	1,650,000	4
.....	.....	.....	.....	Dallas	1,190,000	.....
Utah	9,618,011	-1,085,000	-11	.....	.....	4
Vermont	6,242,254	-1,085,000	-17	.....	.....	3
Virginia	19,584,849	-1,085,000	-6	.....	.....	5

HHS Reallocation of $59.4 million in State Emergency Preparedness Funds for FISCAL YEAR 2004—Continued

State	CDC FISCAL YEAR 2003 Emergency Preparedness Funds	Dollar Amount of Cut to State	Percent Cut From FISCAL YEAR 2003 Funds	Redirected $ for Cities Readiness Initiative		TFAH BT Preparedness Score, Scale of 1–10**
Washington	17,146,134	-1,085,000	-6	Seattle	830,000	6
West Virginia	8,649,835	-1,085,000	-13	.....	.....	4
Wisconsin	15,955,629	-1,085,000	-7	.....	.....	2
Wyoming	6,000,636	-1,085,000	-18	.....	.....	4
** Source:	TFAH's 12/03 Report, Ready or Not? Protecting the Public's Health in the Age of Bioterrorism ***http://healthvamericans.org/state/bioterror/Bioterror.pdf***					

RESPONSES TO QUESTIONS FOR THE RECORD FROM MAJOR GENERAL LESTER MARTINEX-LOPEZ

USAMRMC Responses to Representative Cox's Select Committee Follow-on Questions

Question: 1. How do threat information and vulnerability assessments collected by DHS or DOD influence the research agendas, if at all?

Answer: 1. Within the formal DOD process, the Joint Requirements Office—CBRND (JRO–CBRND) integrates threat information and vulnerability assessments from all sources and reviews the DoD CBD Program. Results of these reviews, conducted with all Services participating, are documented in the Joint Service Modernization and Joint Service RDA Plans. These documents form the basis for the consolidated Program Objectives Memorandum (POM). Once requirements for warlighting capabilities are determined, doctrinal, training, or organizational solutions (nonmaterial solutions) are explored, and when these cannot fulfill the need, equipment or materiel solutions are sought through the materiel acquisition process. Based upon such capability-based analysis, research program strategies are assessed and planning guidance is modified by the CB S&T manager at the Defense Threat Reduction Agency to incorporate potential technological opportunities and needs-based technology maturation efforts into the Department's research agenda. Specifics of how threat information and vulnerability assessments from DHS are incorporated in this process are best directed to the JRO–CBRND.

In parallel to this official process, the interagency coordinating mechanisms described in my response to your question number three also act to shape the detailed research agenda.

Question: 2. Are MRMC researchers and program managers given access to this threat information or allowed to set their own research agendas based on this information?

Answer: 2. In medical CB S&T, MRMC researchers are provided with threat information from multiple sources and this includes raw as well as formal, finished intelligence. Formal intelligence information may be restricted in distribution, but it does shape program and proposal development. MRMC researchers are not allowed to set their own research agendas based on threat information, although they do recommend programs and develop competitive proposals based on such information. Program management of medical CB S&T is the responsibility of DTRA, which was assigned responsibility for management and integration of CBD S&T on 22 April 2003. Program guidance in medical CB S&T is provided by DTRA directly to program executors/performers. Guidance delivered to program performers is developed from DTRA's coordination with JRO–CBRND and the Joint Program Executive Office for CB Defense so that joint Service capabilities and requirements and materiel development strategies are appropriately addressed in developing research agendas. MRMC researchers respond to guidance provided through the DTRA program managers by participating in program development, developing research proposals and executing those that are approved for funding. Final coordination and impacts of proposed program expenditures are discussed between the DTRA program office and MRMC, setting the path for science program execution in the current budget year.

Question: 3. Do the National Institute of Allergy and Infectious Diseases and USAMRIID coordinate on setting research agendas? How would NIAID know whether USAMRIID is pursuing the same pathogen?

Anwser: 3. Using available intelligence, each agency will internally develop and approve its own threat list and research agenda based upon missions and responsibilities. We can expect some threats will be unique to one agency and other threats will be shared. A committee formed by the partners of the National Interagency Biodefense Campus will review and discuss the lists, looking for unique and overlapping threats. Unique threats will be the responsibility of the specific agency; however, the expertise and facilities of other agencies will be available to enhance execution of research and operational programs to address the threats. For overlapping threats, the involved agencies will discuss their approach to the threat, allowing performance of different research and operational programs by different agencies, thereby sharing cost while developing products that will address the threats identified by more than one agency. Needless duplication and redundancy will be avoided in scientific programs through oversight and coordinating efforts of one or more scientific and/or operational committee(s) formed by the partners of the National Interagency Biodefense Campus. Each agency will develop its own programs based upon its missions and responsibilities. The committee will review the programs, looking for redundancy. If redundancy is found, through a joint process, different aspects of the program will be assigned to the agencies with the most expertise and superior facilities in each area. This process will encourage collaboration and mutual fulfillment of research and operational goals, ultimately developing products that can be used by multiple agencies.

In addition to the forums and processes provided by the Interagency Campus, other formal and informal coordination mechanisms will continue. NIAID and USAMRMC leadership participate in activities of the R&D Sub-Group of the Interagency Working Group on Weapons of Mass Destruction Medical Countermeasures of the Chemical, Biological, Radiological, and Nuclear Health Countermeasures Subcommittee of the Homeland and National Security Committee of the National Science and Technology Council. Additionally, USAMRMC's scientific workforce will remain active in providing programmatic and scientific advice to NIAID, and in responding to NIAID program announcements. NIAID program leadership has visited our laboratories for program and scientific briefings on a regular basis. These more formal interactions are facilitated on a personal level by the prevalence of ex-military scientists within the program leadership of NIAID, DHHS and DHS. In addition, the DTRA Medical Chemical and Biological Defense Research Program has initiated efforts to harmonize their science program with leadership within the Biodefense Research Program of the NIAID.

Question: 4. Right now there is no treatment for Ricin exposure—once someone is exposed, they will die. And yet recent experience has shown that it is relatively easy to gather materials and transmit the toxin around the country. This is arguably a more serious threat than anthrax because at least anthrax has a vaccine and a course of treatment. So who has looked at this and determined it's not important to invest in a Ricin treatment? How is this decided?

Answer: 4. Although specific, FDA approved medical countermeasures against ricin are not available at the present time, it is not necessarily true that exposure leads to death. However, after signs/symptoms appear, treatment for ricin aerosol exposure is limited to supportive care to treat acute pulmonary edema and respiratory distress. Supportive care for oral intoxication includes activated charcoal administration and intravenous fluid and electrolyte replacement. Although ricin has historically held a lower level priority as a military threat, based on intelligence estimates and doctrinal reliance on early detection, physical protection and rapid decontamination, the resource intensive nature of such care, and generally poor prognosis, has been a primary consideration in driving a continuing research and development effort for medical countermeasures.

The best medical solution for populations at high risk to ricin exposure would be vaccination because: (1) small amounts of vaccine can provide safe and lasting protection against exposure to large amounts of toxin; (2) vaccines require minimal space and logistical support; and (3) vaccines can be administered easily and far in advance of exposure. Although there is presently no approved human vaccine for ricin, two experimental vaccines have been developed in the DoD Medical Biological Defense Research Program (MBDRP). The candidates have not been tested in humans and do not have current FDA IND status. USAMRIID maintains approximately 30,000 troop effective doses of cGMP dGA (deglycosylated A chain) vaccine candidate that has demonstrated a 90% protection level against 1015 LD50 of aero-

solized ricin toxin in non-human primates. This earlier generation vaccine was developed at a time when human efficacy testing would have been the only way to achieve licensure, and has remained "on-the-shelf" for contingency use as an investigational product. Although the advent of the FDA's "two-animal rule" has technically opened the way for further development, the manufacturing process of dGA is outdated and likely precludes further advanced development A new generation ricin vaccine candidate is presently under development under Defense Technology Objective (DTO) CB.46. This candidate is produced by recombinant technology and is projected for transition to the Joint Program Executive Officer for Chemical and Biological Defense in FY2006.

Research on pretreatment or early treatment (hours to days before or after exposure) has demonstrated initial proof of concept in animals that large amounts of experimental antibodies given as a therapeutic may mitigate ricin toxicity when the toxin is directly injected. However, administration of pre-made antibodies is expected to be less effective against ricin aerosol exposure. The "window of opportunity" for post-exposure treatment with antibodies is narrow because ricio binds and is taken up rapidly by exposed cells lining the airways. An acceleration of these efforts by the DOD would require better definition of the military use for prophylactic antibodies (vs. vaccination) and, as warranted, research and development to produce new human therapeutic antibodies. Although lack of clear military utility for such a therapeutic may limit the military investment in this approach, the USAMRIID is available to partner with other funding agencies is furthering this effort. The development and availability of a ricin therapeutic would certainly have utility for U.S. military personnel exposed to the threat, however a therapy would have even greater applicability for medical defense in a civilian population where the use of prophylactic vaccines may be more difficult to justify.

QUESTIONS FROM THE HONORABLE JIM TURNER FOR ANNA JOHNSON-WINEGAR

Question: 1. Do we have a coherent biodefense strategy today? How should we build one? What should the core elements be? How should its overall goals and objectives be set? What might they look like?

Answer: As of today (June 2004), this nation does not have a coherent biodefense strategy in place. While there has been some effort to develop parts of a comprehensive plan, the planning process has not been inclusive, and the communication of what has been proffered has fallen far short of what is needed. The United States does not need a classified plan that is not available to or understood by the public; this will not be effective in allaying fears and concerns. In order to build a better plan, the administration, working with the appropriate agencies and experts must reach out in a more proactive fashion. Convening Blue Ribbon panels of experts is one step that can take advantage of the various independent thinkers who have been dealing with all aspects of biodefense. Additional Congressional hearings also provide another forum for obtaining information, although these sessions are often limited by time and the results are not well publicized. The overall goals and plans for a biodefense strategy should be developed in a consensus from the component parts. A suggested list (although not comprehensive) would include the intelligence community; medical community; policy experts; communication specialists; and leaders in the scientific and engineering fields. There should be a phased approach, identifying those objectives that can be reached in the short term (less than one year); mid-term (one to three years); and long term (greater than three years). Periodic reports should be issued so that an unbiased, professional analysis can be generated about the progress being made and the availability of funding, personnel and facilities dedicated to the plan.

Increasingly, there are some who see bioterrorism preparedness as a trade-off. That is, funding for public health preparedness for infectious diseases means less money for other functions, such as community health, elderly care or obesity reduction plans. Focusing on a new anthrax or tularemia vaccine means less of a focus on tuberculosis or malaria.

Question: 2. Are these concerns real? Given our experience to date, is it possible to make bioterrorism truly "dual-use"? What can we do better to achieve an all-hazards approach?

Answer: There must be a balance between the emphasis on infectious diseases (both naturally occurring and bioterrorist disseminated) with chronic diseases. The research needs of both communities have common areas of interest and this is the path that must be pursued to make the work truly "dual-use". One easy example is the need for basic research that more clearly defines the immune system and its response to pathogens (regardless of the source of the pathogen). Other examples

include development of generic drugs that can be used to treat a variety of diseases (both acute and chronic), and development of more rapid diagnostic systems.

Funding for public health preparedness for infectious diseases also helps build the infrastructure that will be available to address other concerns. As we learn more about how pathogens interact with the body and how they enter the body (via aerosol dissemination or by mosquito bite), we can apply this knowledge to a broader array of diseases. It doesn't have to be one or the other! There is plenty of work to be done and much can be useful in broad application.

To achieve a better all-hazards approach, we have to stop thinking about one disease at a time. The threat list of bioterrorism agents IS long enough, but the number of diseases on the naturally occurring infectious list, added to those considered chronic is daunting. More emphasis should be placed on multi-valent vaccines, nonspecific immune enhancers, and awareness of general health issues.

The Administration has developed a Biowatch program, deployed in cities throughout the country, and a new biosurveillance initiative, which is to involve building complex new information systems both at DHS and at the Centers for Disease control, known as BioSense. The concept of detecting a release as early as possible makes a lot of sense in terms of protecting the public. But DHS itself admits that the Biowatch system may be too costly and labor intensive. Some scientists have suggested that syndromic surveillance, the basis of BioSense, has not been proven to work.

Question: 3. Are these systems ready to be fielded, or do we need more research and develop better systems first? Are the resources we are devoting to this system well-spent?

Answer: The systems that are fielded today need substantial improvement. First, they are point detectors. The design of these systems only enables filter collection of air samples from a limited area in the immediate vicinity of the collector. Therefore, it is critical to place the detector system in the optimal location. Without knowing where an attack may occur, this is simply a guess. There are a number of computer projections that determine the minimal number of systems needed to cover a given area (a city, or a military installation), but the number in use today is far below the minimum for each location. The systems are indeed labor intensive, and require sophisticated laboratory analysis of the filters to determine presence of a biological agent. Sustainment costs for these systems are very high. The resources being spent on these systems is not well spent since they are not fully developed, are prone to false positives, require extensive quantities of consumable expensive reagents and are not necessarily located in the right places.

Question: 4. Are these the best we can do in detection, or are there other options we should be considering?

Answer: The systems in use today in the Biowatch program are among the best available. However, the assays in use are based on specific reagents, which, by definition, limit the scope of the system. In other words, you have to know what you're looking for, then develop the right reagents, and maintain the system accordingly. As the list of potential I bioterrorist threats increases, more reagents must be developed and added to the existing array. While the reagents available today cover most of the highest probability threats, they are certainly not comprehensive. In addition, the level of sensitivity needs to be improved by several orders of magnitude to approach maximal effectiveness. A bigger concern is the lack of absolute correlation between competing systems developed by different laboratories. There is currently no federal agency or organization that is the certifying group for these types of reagents. When different results are obtained (one positive, one negative), the credibility of detector systems comes into question. More research is needed in stand-off detection for biological agents. Approaches include various types of spectroscopy and lasers to probe and interrogate potential agent clouds. These types of systems are not ready for even preliminary fielding, but should be the option of choice for future work.

With regard to biosurveillance, I agree that this has not yet been proven to work. In concept, the idea is good, but it will be costly to develop the information systems that can collect and coordinate the input from private physicians, hospitals, schools, drug stores, and all the other contributing elements. Since the possibility exists that the first cases of a bioterrorist attack may show up in very dispersed areas (i.e. assume the release of an agent in an airport with symptoms not beginning for 24 hours), it will be critical for BioSense to capture data from extensive geographical areas. While the CDC seems the appropriate organization to collect and analyze the data, they are not currently staffed to undertake this responsibility. Submission of data to the system will be voluntary and there is no real mechanism to monitor compliance. The costs associated with this type of passive system have not been

fully evaluated. Finally, issues of patient confidentiality have not been suffiiently addressed.

In your testimony, you mentioned that even with perfect detectors, we need a robust "concept of operations" to make that detector part of a real working system that will improve our biosecurity. That seems to be exactly what we lacked during the anthrax attacks. Once the attack was detected here or in Florida, or New York, no one seemed to know quite how to respond, or what to tell the public.

Question: 5. Do we have a better "concept of operations" today behind our civilian biodetection systems, particularly Biowatch?

Answer: I believe we have made progress in establishing a better concept of operations. Coordination with state and local officials has been an important advance in our understanding of how results from Biowatch would be reported and utilized throughout the nation. Various training exercises have been completed which provide the foundation for a comprehensive approach. These efforts must be continued so that confidence in the systems can be improved.

Most biodefense programs before 9/11 were carried out by the Department of Defense. You pointed out in your testimony that funding for medical countermeasures has grown exponentially following 9/11, but that this growth has primarily occurred at other agencies, NIAID now has a $1.7 billion budget, far larger than USAMRIID's $66.3 million, and even larger than DOD's entire chemical and biological defense research budget, including medical and non-medical projects, of $359.3 in FY04.

Question: 6. Let's say you were back at DOD, but with a budget of$7.3 billion, the combined NIAID and Bioshield budgets. What would you do differently than we are doing today?

Answer: As you are aware, the NIAID and BioShield budgets encompass only medical research and procurement of medical countermeasures. I would reallocate more research funding into the non-medical components of a comprehensive program. This would include more work on stand-off biodetection; development of better decontamination solutions; and more efforts in modeling and simulation to understand dispersion of biological agents. There are many unanswered questions about aerosol dissemination of biological agents. Much of the work today relies on data generated 50 years ago or more, including estimates of the LD50 for humans (e.g., is the estimate of 10,000 anthrax spores the correct LD50 for humans, or is it lower in some individuals?), early clinical signs for many agents, and estimates about survivability of biological agents in various delivery forms. In addition, I would rearrange the emphasis of the medical funding to focus on development of appropriate animal models and to expand the funding available for necessary clinical trials for safety and immunogenicity of potential new countermeasures. As I stated during the hearing, I think the NIAID approach toward basic science that is investigator initiated will not lead to many new products. Conversely, the BioShield legislation allows for procurement of medical countermeasures that are near FDA licensure. There is an obvious gap in the work since there is not any focus on pivotal animal studies and development of surrogate markers to establish immunity in humans. Making effective transitions from laboratory scale basic research into production quantities of effective countermeasures should be a high priority for developmental funding.

Government Owned- Contractor Operated Facilities

Question: 7. What is a GOCO facility for medical countermeasure development?

Answer: During the first Gulf War (1990–91), the DOD needed larger supplies of several medical countermeasures for biological agents, primarily anthrax vaccine and botulinum toxoid. The only manufacturer at the time (the Michigan Department of Public Health, subsequently BioPort) had limited facilities and while they worked diligently to increase production, they were unable to meet the needs of the United States military, much less any Allies or coalition partners. The DOD commissioned a special task force (code named Project Badger) that contacted all commercial vaccine manufacturers to assess their interest and willingness to produce extra doses of these critical vaccines. None were responsive due to limited availability of facilities; concerns about liability and indemnification; concerns about long-term funding for the effort; concerns about safety; need for bio-containment laboratories (BL–3 required) and lack of specialized, dedicated equipment needed for these products. (There is an FDA regulation that any product made from a spore-forming organism, such as *Bacillus anthracis* or *Clostridium botulinum* must be produced in dedicated equipment that can not be used subsequently for other vaccines). .

Ultimately, the Project Badger report recommended that DOD pursue the option of establishing a stand-alone Vaccine Production Facility. The best option appeared to be a facility that was government owned (and funded), but .operated by contractors since DOD lacked sufficient personnel to staff such a facility. The complete Project Badger report has now been declassified and is available for your review. Following the Project Badger recommendation, the Army developed costs, evaluated potential locations, and ultimately, the DOD submitted a budget for a VPF in the POM. A small amount of funding ($25 million) was appropriated in FY02 for design studies, but after further review, the project was deleted from the DOD budget request.

Question: 8. How would the use of this kind of facility differ from the BioShield approach? How would it differ from the approach NIH is taking to product development?

Answer: The GOCO approach requires construction of a stand alone facility that will be owned by the government. Both the BioShield and NIH approaches rely on use of existing industrial facilities. Although the pharmaceutical firms seem opposed to the GOCO approach, citing the availability of capacity already existing, this belies that fact that each year industry has difficulty meeting existing market demands. Recent shortages in tetanus, pertussis, and flu vaccines support the perception that there is no excess capacity available for biodefense vaccine work. While scheduling production runs of various products is not a trivial exercise, the profitability and marketability of a specific item seem to be high priorities. There is genuine concern that the existing facilities will be taxed (at over 80% capacity) to meet current needs for widely used products, ranging from influenza vaccine to the childhood vaccines.

The GOCO approach also differs from current alternatives in that both NIB and the BioShield approach require a specific solicitation for each product. The RFP process is time consuming and mandates that potential contractors spend time developing a proposal and negotiating final specifications. In the GOCO approach, a long-term contract (10 years or more) is envisioned, with annual funding for the workforce salaries, supplies, validation and licensing costs, etc. The actual product(s) to be produced each year can be decided on as-needed basis, rather than projecting far in advance. This provides much more flexibility to the government. Also, by making a long-term commitment to a GOCO, the government sends a strong signal about sustained support for medical countermeasures for biological agents. Referring back to the "dual-use" question above, the GOCO facility should be considered a national asset. While development and production of bio-defense products would be the first priority, this facility would be available as a back-up to industry for either surge production of a particular vaccine, or as an alternative should a current production facility be closed for renovation or because of FDA violations identified during routine inspections. Since the nation finds itself in a position where there are fewer licensed vaccine manufacturers than ever before, and since many products are made in only one facility (raising vulnerability), the concept of a back-up facility should be considered an attractive alternative.

The GOCO facility should be designed as a multi-functional building, with several types of production suites (e.g., bacterial fermentation; tissue culture in roller bottles; etc); pilot development scale laboratories; common areas for bottling and storage of final products; appropriate containment laboratories for animal testing of candidate vaccines; and other required functions. The understanding is that the facility would be totally regulated and inspected by the Food and Drug Administration, thereby assuring high quality products with external review. Validation of the facility and all the equipment and processes is a complex process and could take several years after completion and trial runs. The facility would not normally compete with private industry, thus allaying their concerns about profit, but would serve as an adjunct to the current concepts.

Question: 9. Should Congress still consider a GOCO facility?

Answer: While there are still issues to be resolved, such as which department should be in charges of a GOCO facility, I firmly believe this is the right approach for the government. The key features of a GOCO facility include the following:

- government control of production, availability, and distribution
- flexibility for emergency production technologies
- meets national security priorities for bio-defense vaccines
- overcomes limited industry interest in bio-defense products
- existing government labs provide supporting research and development
- operating contractor would provide specialized expertise in vaccine production and regulatory requirements

At the time of the original proposal in the early to mid 1990's, a GOCO facility was estimated to cost only $125 million for construction. The revised estimate prepared by the DOD in 2000 estimated $856.5 million for design and construction, with annual operating costs to be added to this figure. As time passes, the costs will only increase, and the nation will be at the mercy of the fragile, profit-motivated pharmaceutical industry to make the bio-defense vaccines that are needed. In my opinion, Congress should strongly consider appropriating funds for a GOCO facility for bio-defense medical countermeasures.

The National Biosecurity Analysis and Countermeasures Center (NBACC) at the Department of Homeland Security will be responsible for assessing the threat of bioterrorism. I'm interested in hearing from you about the mission of this institution.

Question: 10. What capabilities will NBACC bring that DOD did not have during the last several decades? Is this a wholly new function, or something of a duplication of national security functions, but for homeland defense?

Answer: The Department of Defense program in biological defense over the past decades (since 1969 when President Nixon ended the U.S. offensive biological warfare program) has been purely defensive in nature. It has been a reactive, not a proactive program. The capabilities envisioned for NBACC position it to be more proactive in conducting the appropriate kinds of studies and analyses to validate threats and make more realistic predictions about the use of biological agents. For example, the work done following the anthrax attacks in the fall of 2001 on how the anthrax ,spores were released through the letters and the mail sorting machines, as well as how effectively radiation could be used to kin the spores in the mail, is work that does not fall under the mission of the DOD biodefense program. Other work needs to be completed on assessing the infective doses of some biological agents via the respiratory route since current estimates are based on outdated methods for enumerating organisms and assessing viability. In addition, NBACC should assume the responsibility for maintaining data bases with information on multiple strains of organisms such as anthrax. The DNA sequencing of many pathogens is underway, and NBACC should use this data in their forensic responsibilities. While there may be some overlap between the national security function of DOD and the NBACC mission, I believe the NBACC mission surpasses the limited role of the DOD. Clearly, there must be a coordination of efforts between these agencies, as well as the intelligence community for NBACC to be successful.

Another issue I want to ask you about is how NBACC should carry out its duties. There is significant concern about the potential for new technologies in biology to be applied to create a more dangerous bioterror threat. Many are concerned that these experiments should never be tried, and, if they occur accidentally, the results kept secret.

Question: 11. How exactly should NBACC assess the assessment of this threat? Should NBACC attempt to create some of these more dangerous pathogens, or refine techniques for weaponization? Is there a situation where such experiments are legitimate?

Answer: Since there are no restrictions on terrorists, it would be prudent for an organization such as NBACC to be able to analyze experiments that have been reported in the open scientific literature to determine widespread applicability. One immediate example that comes to mind would be for NBACC to perform the studies that determine whether currently available vaccines (such as anthrax vaccine) are effective in protecting against all strains of the organism that exist in nature. Following this, efforts should be made to obtain samples of genetically modified organisms (such as that reported by the Soviets) to test the effectiveness of our detectors and medical countermeasures. In the absence of such confirmatory data, we are only deluding ourselves about the breadth and depth of our protection. Reproducing the laboratory work of others, and conducting some well controlled experiments to evaluate the ease of production of new more potent organisms are appropriate for the mission of NBACC, in my opinion.

There is a great deal of controversy in the scientific community about restrictions on publishing data on biological agents. While the "publish or perish" philosophy exists in

Question: 15. Should we be worried about Russian biological programs? Is there more the United States should be doing at former bioweapons sites in the former Soviet Union?

Answer: I have limited knowledge of the activities the United States is pursuing in the former Soviet Union, and would defer this question to those with more expertise. However, my belief is that the former Soviet Union (along with other counties)

maintains a robust research program in biological warfare. The limited program underway to convert former bioweapons sites to peaceful objectives is slow due to administrative issues and reluctance to accept new goals and objectives. Retraining scientists and technicians will take a matter of years, and the ultimate success of the program depends upon continued financial support coupled with appropriate levels of monitoring for safety and security. In my opinion, the individuals participating in these programs can be motivated by financial security, the opportunity to publish their findings in the open scientific literature, and the opportunity to participate as equals in international scientific conferences.

NO RESPONSES TO THE FOLLOWING QUESTIONS HAVE BEEN RECIEVED:

QUESTIONS FOR THE RECORD FROM RANKING MEMBER JIM TURNER, FOR DR. ANTHONY S. FAUCI

1. The Administration's recent "Biodefense for the 21st Century" strategy document indicated that HHS is responsible for the "anticipation of future threats?" What will HHS do in this area and how will it differ from the work at NBACC?

According the Homeland Security Act, HHS is to work collaboratively with DHS as its sets goals and policies for medical countermeasures development. You have indicated in your testimony how this is occurring. DHS is also working with USDA on developing veterinary medical countermeasures to counteract agroterrorism.

2. Can you describe the difference between how these two inter-agency countermeasures research programs are managed, and whether one is working better than the other?

3. How do threat information and vulnerability assessments collected by DHS influence the research agendas, if at all?

4. Are NIH researchers and program managers given access to this threat information or allowed to set their own research agendas based on this information?

5. Do the National Institute of Allergy and Infectious Diseases and USAMRIID coordinate on setting research agendas? How would NIAID know whether USAMRIID is pursuing the same pathogen?

6. Right now there is no treatment for Ricin exposure-once someone is exposed, they will die. And yet recent experience has shown that it is relatively easy to gather materials and transmit the toxin around the country. This is arguably a more serious threat than anthrax because at least anthrax has a vaccine and a course of treatment. So who has looked at this and determined it's not important to invest in a Ricin treatment? How is this decided?

It seems that thus far our biodefense strategy has largely been driven by the nation's vulnerability to a mass-casualty attack, such as terrorist use of smallpox or a large airborne anthrax release. This is reflected in the categorization of agents on the A, B, and C priority pathogen lists from Centers for Disease Control—with smallpox and anthrax on the A list.

However, the anthrax letter attacks in October, 2001 suggest we may need to pay attention to small- and medium-sized attacks, too. The Congressional Research Service has done such an assessment, and, interestingly, anthrax and smallpox were not at the top of the list. Instead, they determined glanders was the top concern, currently a category B agent.

7. Are you aware of this assessment, and if so, what do you think of it? Does the current priority listing of pathogens need to be reassessed? Has it been reassessed? Who would be responsible for such a reassessment and when and how will it get done?

Project Bioshield

8. Will the implementation of Project Bioshield change the way NIAID spends its biodefense budget?

9. Will you continue to fund advanced development of countermeasures, such as the new anthrax and smallpox vaccine projects, or will you leave it to the guaranteed market under Bioshield to lead to development?

Anthrax Vaccine

10. What is the justification for a new anthrax vaccine (rPA) when there is already an FDA approved vaccine (A V A) that has been used for years by the military?

11. Is it true that the new vaccine is similar to the existing vaccine in terms of safety, efficacy, and delivery? Please consider the purpose and results of the CDC anthrax vaccine safety and efficacy research program in your answer.

12. Please explain why the development and purchase of rPA for the stockpile is, at this time, a better investment than either (a) purchase of A V A for the stockpile, or (b) research and development of an oral or other advanced vaccine.

NIB has obligated nearly $750 million for the construction of new, high security biodefense labs around the nation, so-called BSL–3 and BSL–4 labs. In addition, the CDC, the Department of Agriculture, the Department of Defense, the Department of Energy, and the Department of Homeland Security are all planning to construct new facilities.

13. What study was conducted to determine our requirements for BSL laboratory space? What were the conclusions of that study in terms of how much space is needed?

14. Communities are rightly concerned about the possible escape of a harmful pathogen from one of these labs. We need only reference the recent escape of SARS from a Chinese research lab to know that it is possible. What protocols are in place to protect communities from an accidental release of a harmful or lethal pathogen?

QUESTIONS FOR THE RECORD FROM REPRESENTATIVE NITA LOWEY FOR DR. ANTHONY S. FAUCI

1. Can you please tell the Committee what is being done to support the development and deployment of radiological medical countermeasures? No response has been received.

It is my understanding that the Department of Health and Human Services has issued two requests for information (RFI)—one from the Centers for Disease Control and Prevention in February 2004 and one from the National Institute of Allergy and Infectious Diseases in April 2004—regarding the development of radiological countermeasures.

2. Considering the Attorney General's recently mentioned threats, can you please explain the need for two different RFIss rather than a request for proposals (RFP)? No response has been received.